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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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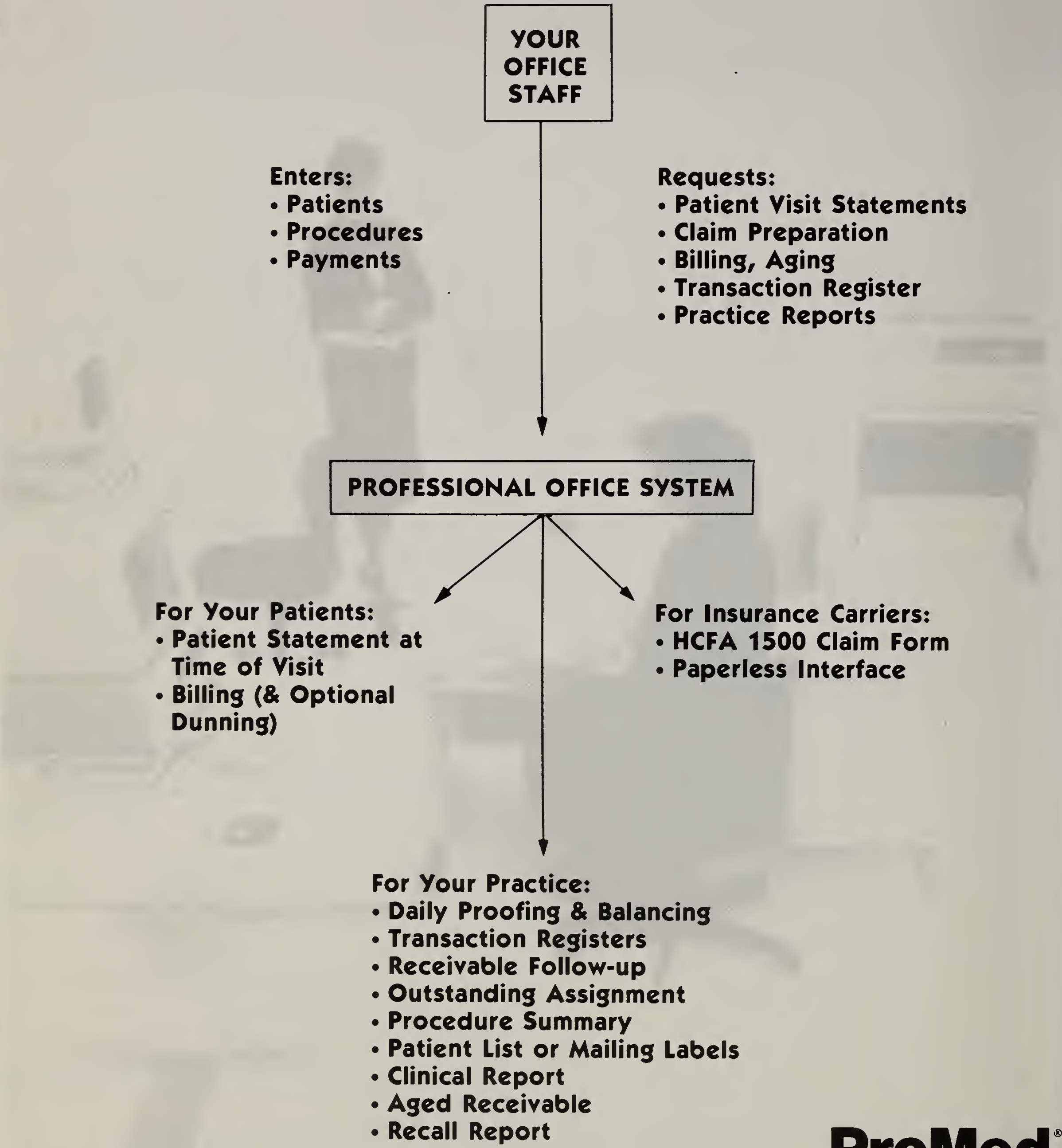**ProMed®. . .The Medical Practice Management System**

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Diagnosis of Ruptured Abdominal Aortic Aneurysm

MAGRUDER C. DONALDSON, M.D., JOEL M. ROSENBERG, M.D.
AND CHARLES A. BUCKNAM, M.D.

ABSTRACT—Rupture of abdominal aortic aneurysms is associated with high mortality in spite of advances in elective surgical therapy of vascular diseases. Rapid intervention is mandatory for improved chances of survival, but difficulties in diagnosis sometimes delay timely therapy. Unusual manifestations of rupture may occur which are particularly misleading. Nonetheless, proof by physical or radiologic exam that an aneurysm exists, together with pain or abdominal tenderness, will lead to a correct diagnosis in the overwhelming majority of patients, regardless of other less common and peripheral signs and symptoms.

Rupture of an aneurysm of the abdominal aorta is a lethal event. Untreated, the outcome is uniformly fatal, and even with surgical intervention mortality remains between 14 and 58 percent.[1-7] The problem occurs in an elderly population with multisystem disease, and superimposition of circulatory collapse is a disastrous burden which places the patient and his medical team at a great disadvantage. The high mortality for surgery of ruptured aneurysms is all the more distressing in the face of such excellent results for elective operation. Currently, many hospitals are able to perform elective resection with mortality rates below 5 percent.[8] Clearly, such elective therapy in well prepared patients with aneurysms that pose a significant threat of rupture is to be preferred.

The crux of surgical therapy of ruptured abdominal aortic aneurysm (AAA) is rapid control of the leaking aorta with flawless surgical technique. Meeting this goal depends on prompt diagnosis, quick response of the operating room team and surgical expertise. One of the most difficult aspects of this formula is recognition of the disease, since it may masquerade in many different clothes.[9,10]

Pathology

Abdominal aortic aneurysms may remain clinically quiescent for many years. Once formed, they generally enlarge at variable and unpredictable rates averaging between 0.26 and 1.12 centimeters per year.[11] In general, the larger the aneurysm becomes, the higher the risk of becoming symptomatic. Aside from occasional embolic phenomena and erosion or compression of adjacent structures, symptoms are invariably associated with rupture or impending rupture.

Aneurysms generally have layers of laminated clot within their wall. Should this clot become disrupted, there may be penetration of liquid blood under the clot which can cause symptoms without rupture. Though the term "dissection" has been used to describe this event, the term is best left to describe insinuation of blood under the intima or into the media of arteries, such as occurs most commonly in the thoracic aorta. Occasionally, abdominal aortic aneurysms may expand acutely, producing symptoms.

The adjectives "ruptured" and "leaking" are synonymous, and describe extravasation of blood beyond the walls of the aneurysm. Such extravasation occurs most often into the retroperitoneal tissues posteriorly or posterolaterally. In 5 to 15 percent of patients, blood extravasates freely into the peritoneal cavity, either directly from the aorta, or by secondary rupture of the retroperitoneal hematoma. Rarely, the aneurysm may rupture into the distal duodenum, other segments of small or large bowel, the vena cava or ureter. A retroperitoneal hematoma may remain stable for a number of hours or rarely even days before finally extending. Rupture into the free peritoneal cavity produces rapid hypovolemia. Rupture into a viscus, though it can be disastrous, may be associated with only moderate loss of blood which can occur intermittently.

MAGRUDER C. DONALDSON, M.D., Assistant Professor of Surgery, Department of Surgery, University of Connecticut School of Medicine and John Dempsey Hospital, Farmington, CT. JOEL M. ROSENBERG, M.D., Chief Resident, Department of Surgery, Hartford Hospital, Hartford, CT. CHARLES A. BUCKNAM, M.D., Assistant Clinical Professor, Department of Surgery, University of Connecticut School of Medicine and the Hartford Hospital.

Reprint requests to: Department of Surgery, University of Connecticut School of Medicine, 263 Farmington Ave., Farmington, CT 06032 (Dr. Donaldson).

Clinical Presentation

The most common single symptom in patients with ruptured AAA is unremitting abdominal or back pain (Table 1). There may be radiation of pain into one or both groins and occasionally into the upper thigh with findings of femoral neuropathy. Pain accompanied by a history of known AAA or by a pulsatile abdominal mass is almost pathognomonic. Tenderness of the mass, aorta or epigastrium is almost always present, though occasionally with a small posterior leak this may not be apparent. Finally, there will often be a history of weakness, light headedness, faintness, collapse or nausea and vomiting consistent with acute hypovolemia. These symptoms are usually transient, in that recumbency and temporary tamponade will allow restoration of more normal circulating volume. Pain continues unabated, however, as does the tenderness.

Table 1

SIGNS AND SYMPTOMS OF RUPTURED AAA

Reference No.	*1*	*2*	*3*	*4*	*10*	*Authors' Series*
No. Patients	87	151	105	92	44	81
Pain(%)	89	84	"most"	100	93	98
Abdominal	77	–	–	65	55	57
Back	43	51	–	68	48	72
Groin/Flank	10	–	11	–	22	–
Leg	3	–	–	4	23	–
Tenderness(%)	–	–	–	–	91	78
Mass(%)	–	–	87	100*	82	91
Shock(%)	40	71	40	35	34	57
+KUB	78	–	–	89	–	75

*all 40 patients in whom records indicated mass was sought

Though the presence of a tender pulsatile abdominal mass in a patient complaining of low back pain and light-headedness with a history of a known AAA is a highly specific diagnostic picture, any one component exaggerated out of proportion to or in the absence of others may lead to confusion. This is particularly so if the patient is in shock or obtunded and unable to give a clear history or reliable findings during examination. Furthermore, collapse from ruptured AAA may precipitate secondary pathology such as myocardial ischemia which clouds the picture.

Myocardial infarction or pulmonary embolus are perhaps the most commonly mistaken entities in the differential diagnosis, with true dissection of the thoracic aorta, pancreatitis, biliary disease, perforated duodenal ulcer and mesenteric infarction also important. Retroperitoneal neoplasm may present as a tender pulsatile mass.[12] Acute musculoskeletal back conditions, lumbar radiculopathy, arthritis, Stokes-Adams or cerebrovascular transient ischemic attacks may also be suspect. Unusual rupture of the AAA into a viscus can be confusing, presenting as gastrointestinal bleeding in the case of fistula to the bowel and gross hematuria with a connection to the ureter.

Hypotension, though often present, is non-specific. Many patients will be normotensive and well perfused. Presence or absence of a bruit in the abdomen or pulses in the peripheral vascular tree have no bearing on the diagnosis of AAA. With a retroperitoneal hematoma, the abdomen may be silent without peristalsis, and there may be evidence of psoas muscle irritation. As mentioned before, rarely there will be objective evidence of femoral neuropathy.[13] Incarceration of an inguinal hernia can be caused by a combination of ileus and retroperitoneal hematoma from ruptured AAA.[14,15] If the aneurysm has been ruptured for a day or more, the hematoma can dissect and present as ecchymosis in the flank or perineum. In the presence of aortocaval fistula, a constant machinery murmur will be audible over the abdomen, and there will be evidence of venous hypertension in the lower half of the body, along with other objective signs of increased cardiac output and possible cardiac overload.[16]

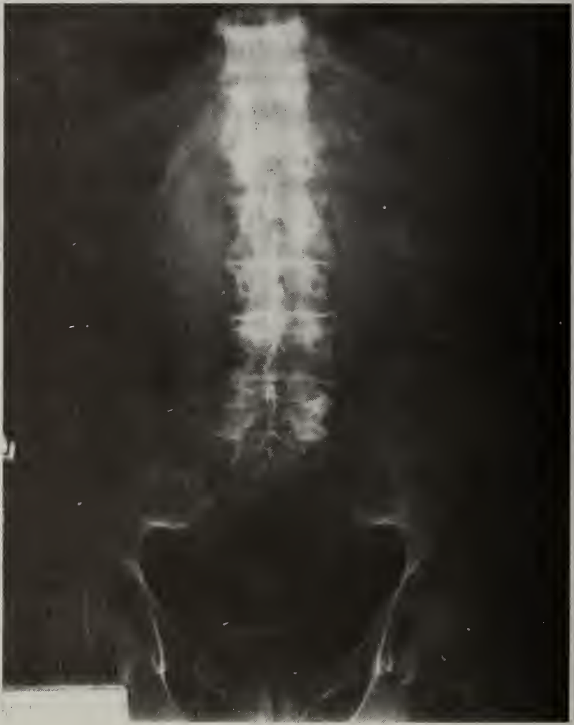

Figure 1

Plain abdominal xray demonstrates bilateral absence of psoas shadows due to retroperitoneal hematoma after rupture.

Laboratory

Laboratory examination should be used judiciously in order to confirm the presence of an aneurysm and to exclude the presence of any other possible diagnoses or complications of rupture. Perhaps the most useful way to confirm the presence of an aneurysm is with a plain abdominal Xray which will reveal calcifications in the wall of the aorta, absence of the psoas shadow or other findings consistent with retroperitoneal hematoma in a large percentage of cases (Figure 1).[17] Ultrasound is also an excellent way to diagnose the presence of an aneurysm, often demonstrating retroperitoneal hematoma and localizing the superior border of the aneurysm in relation to the renal arteries (Figure 2).[18, 19] Both of these tests are relatively specific, safe and rapid. Computerized tomography has been recommended, and is coming into increasing use at this time.[20] It should have a high level of accuracy, but is usually more time-consuming and may not be necessary after a combination of flat plate and ultrasound. Arteriography has been employed by some,[12] particularly in confusing situations, but its routine use is probably not indicated. Arteriography will rarely show a leak, and may not even demonstrate the aneurysm since laminar clot can make the profile of the lumen appear normal.

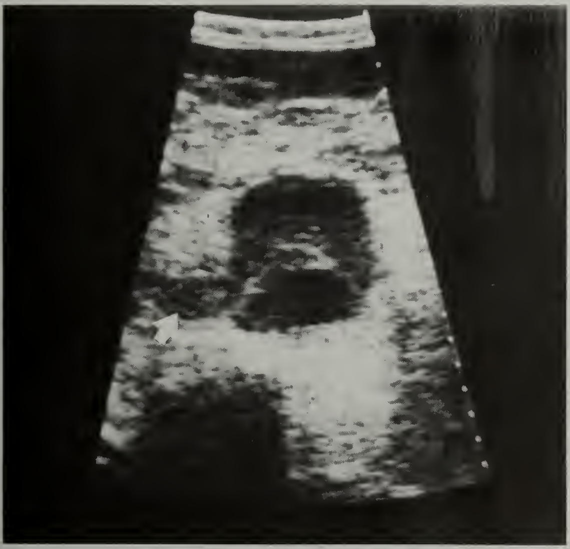

Figure 2
Transverse section of ruptured AAA by ultrasound demonstrates 5.5 cm AAA with organized mural thrombus surrounding central lumen and posterolateral hematoma (arrow).

Hematocrit levels will generally be diminished to some degree in the presence of rupture. In the acute phase of leakage, however, there may be no hematocrit change. White blood cell count is elevated in most instances. Other tests are generally not helpful in making the diagnosis of rupture, though chest Xray, EKG, serum chemistries including amylase, urinalysis, blood bank sample and arterial blood gases should be drawn to help in resuscitating an obviously ill patient and to help rule out other diagnostic possibilities.

Conclusion

It should be realized that most often the diagnosis is clear from the history and physical examination, and because institution of surgical therapy is paramount, excessive testing may be a disservice to the patient. The most important step in diagnosis is to simply consider it as a possibility, because one may be led off the track very early towards other disorders such as myocardial infarction, perforated ulcer, pancreatitis or renal stone. Even when the possibility of ruptured aneurysm is in mind, the disease may present with confusing signs and symptoms though none of these potentially misleading findings will be present in the absence of an aneurysm. Indeed, given any one of the triad of typical pain, abdominal tenderness and a pulsatile abdominal mass, rupture of an AAA should be at the top of the differential diagnostic list. Direct confirmation of the presence of an aneurysm in the abdominal aorta by physical examination and flat plate or ultrasound in association with one of these three cardinal indices is almost always sufficient evidence to warrant rapid exploratory laparotomy without delay for added diagnostic testing.

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Chemotherapy of Testicular Cancer at Yale: 1976-1982

JAMES LIN, M.D. AND JOSEPH R. BERTINO, M.D.

Testicular carcinoma accounts for approximately one percent of all male cancers. Its importance lies in the fact that it is the most common malignancy in young men 15 to 39 years of age and accounts for over 10% of cancer deaths in that age group. Furthermore, since the advent of combination chemotherapy incorporating cis-platinum, it is one of the few solid tumors which is curable in the majority of patients even with advanced disease.[1-5] A staging system which is commonly used for testicular carcinoma is that of Einhorn and Donahue (Table 1).[1] In stage I disease, the cure rate is nearly 100%, and in stage II disease, when combination chemotherapy is used either as an adjuvant or to salvage a relapse, the cure rate is greater than 90%. Stage III disease is further subdivided by the presence or absence of poor pronostic features (Table 2).[1-8] The results from the literature give a 65-80% complete remission (CR) rate overall with 10-15% relapses. In the absence of poor prognostic features, the CR rises to 85-100%, whereas if these features are present, the CR falls to 50-65%.[1-8]

Table 1

STAGING OF TESTICULAR CARCINOMA

I–	limited to the testicle
II–	involvement of retroperitoneal nodes
	A-<5 nodes and largest node ≤2 cm diameter
	B->5 nodes involved or largest node >2 cm diameter
	C-"gross" abdominal disease
III–	distant metastases

Table 2

POOR PROGNOSTIC FEATURES IN STAGE III DISEASE

1. "Bulky" disease
    a) abdominal–palpable mass or liver mets
    b) pulmonary–mets >2 cm in diameter or >5 mets per lung
2. Extragonadal primary
3. Visceral metastases–e.g. brain
4. Marked elevations of serum markers

We have recently reviewed the Yale experience with combination chemotherapy in the treatment of testicular carcinomas from 1976, the first year that cis-platinum was used at Yale in combined regimens, to 1982. As summarized in Table 3, 87 patients with testicular neoplasms of all stages were seen at Yale-New Haven Hospital during this period of time. Of these, 31 patients received chemotherapy for testicular carcinoma at Yale. By chart review, contact with the patients' physicians or the patients themselves, we obtained follow-up on all but one of the patients up through July, 1983, with most of these patients having been followed for two years or more from the completion of chemotherapy. Although relapses have occurred after a disease-free period of greater than two years,[9] including one in this series, they are unusual.

The age distribution of patients seen at Yale was similar to that reported elsewhere with most patients being 20 to 50 years of age. The overall results of chemotherapy at Yale are shown in Table 4. As can be seen, treatment of stage II disease was highly successful, however the results for stage III disease are worse than expected. Part of the reason is that a disproportionate number of patients (9 of 13) had poor prognostic indicators. However, when stage III patients were subdivided into poor vs. good prognosis categories, the results were still disappointing, with only 2 of 4 patients

JAMES LIN, M.D., Postdoctoral Fellow, Section of Medical Oncology, Department of Internal Medicine; JOSEPH R. BERTINO, M.D., American Society Professor of Medicine and Pharmacology and Chief, Section of Medical Oncology, Department of Internal Medicine; both of the Yale University School of Medicine, New Haven, CT.

with good prognosis disease successfully treated (50%) and 2 of 9 patients with poor prognosis indicators disease successfully treated (22%), although the numbers are too small to be statistically significant.

Table 3

CHEMOTHERAPY OF TESTICULAR CANCER AT YALE 1976-1982

Total patients	87	84 germ cell tumors, 2 extragonodal primaries 2 lymphomas 1 rhabdomyosarcoma
Stage I	45	
Stage II	25	18 chemotherapy at Yale 4 RT 2 referred elsewhere 1 followed without therapy
Stage III	14	13 chemotherapy at Yale 1 referred elsewhere
	84	total

Table 4

RESULTS OF CHEMOTHERAPY AT YALE

Stage II (18 patients)
16 NED (89%)
1 dead of MI, clinically NED* at time of death
1 lost to follow-up
Stage III (13 patients)—2 extragonodal primaries
4 NED (31%)
7 dead of disease
1 dead of cardiopulmonary arrest, recurrent disease at time of death

*NED = No evidence of disease

Further analysis of the chemotherapy was revealing. As Table 5 shows, one patient had already failed previous treatment with VAB IV, a platinum containing regimen, 2 patients did not receive platinum due to renal failure or age, one had rapidly progressive and widespread disease, and died shortly after initiation of therapy, and one patient who did not receive cisplatinum was a late relapse. Thus, when we consider only stage III patients who received adequate chemotherapy with a platinum containing regimen, we find that of patients with non-bulky disease, 2/3 are NED, and of patients with bulky disease, 2/6 are NED, which is comparable to results in the literature.

Conclusions and Prospects

Unlike most reports in the literature, which describe the results of clinical trials, our series includes every patient with a germ cell tumor who was treated with chemotherapy at Yale. Thus, it includes patients that would have been excluded from a clinical trial because of age, renal function abnormalities or poor performance status, and this is reflected in the poorer overall results in patients with advanced disease. On the other hand, it could be argued that these results are a better indication of what can be achieved in clinical practice.

The development of cisplatin as a chemotherapeutic agent has had a major impact on the treatment of patients with testicular cancer. A large percentage of patients with advanced disease are curable if treated adequately with the combination regimen that includes cisplatin, vinblastine and bleomycin. It is also clear that the current treatment regimen is not as effective in patients with identifiable poor prognostic indicators, and new programs are required. Encouraging results have been obtained with a new agents, such as VP-16 (etoposide),[9-12] ifosphamide[12] in combination with cisplatin, and with higher doses of cisplatin administered with hypertonic saline.[13] Thus attention is being directed in this center as well as elsewhere to more effective treatment of patients with poor prognostic features, and to "salvage therapy" for patients who fail the VBP program.

Table 5

CHEMOTHERAPY OF STAGE III DISEASE

VBP	7	2 non-bulky—2/2 NED 5 bulky— 1/5 NED 3/5 died of disease 1/5 died of cardiac arrest, in relapse
VBP × 2; Bleo, Adria, CDDP, VP-16		1 NED, "bulky" disease
CDDP, Velban, MTX, Ara C		1 failed previous chemo with VAB IV, non-bulky disease
CDDP, Velban, Act D, Cytoxan		1 bulky disease, HCG = 980, 148, died <1 week after treatment
Act D, Bleo, VP-16		1 bulky disease, creatinine clearance = 16 cc/min.
Cytoxan × 8, Velban × 2, Adria and CDDP		1 non-bulky disease, clinically NED 11/79 to 9/82, liver and peritoneal disease at autopsy 12/82
Cytoxan		1 mediastinal primary "bulky" disease in 71 year old patient

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Low Anterior vs. Abdominoperineal Resection

A Community Hospital Experience

UMBERTO CAPUANO, M.D. AND DAVID WALTERS, M.D.

Introduction

Controversy exists in the recent surgical literature concerning the treatment of midrectal carcinomas. The choice of abdominoperineal resection (APR) for low rectal lesions, those situated 0-5 cm. from the anal verge, and low anterior resection (LAR) for upper rectal lesions, those situated 11-17 cm. from the anal verge, has become generally accepted at major academic centers.[1,2] The treatment of midrectal lesions has, however, remained uncertain. As early as 1961, Deddish and Stearns demonstrated better five-year survival rates when low anterior resection was used for carcinomas in the 6-10 cm. range.[3] Recent studies by the American College of Surgeons, however, have shown that one-third of surgeons continue to use APR for the excision of upper rectal lesions. Furthermore, one-half continue to use this procedure for mid-rectal lesions.[1,2]

An additional variable has entered this equation in the last few years with the introduction of the end-to-end anastomosis (EEA) stapler at many community hospitals. This device has enabled surgeons to extend the technical feasibility of LAR by facilitating the construction of low pelvic anastomoses. In this setting, compromise of adequate cancer resection becomes a distinct possibility. The data presented here were gathered to address the treatment of midrectal carcinomas at a medical school-affiliated community hospital. The adequate transfer of current surgical teaching from large centers to the community hospital is assessed by two parameters: the procedure of choice for resecting midrectal carcinomas and the role of the EEA stapler in making that choice.

Methods

Three hundred and two charts were reviewed from the St. Francis Hospital Tumor Registry in a period extending from 1978-1982. Data collection focused on location of the lesions, Duke's staging, and operative technique used for excision. Five-year followup statistics were sacrificed in order to examine the period in which the stapler became available and modified treatment options.

Results

The final study group contains 110 cases, 54 APR's and 56 LAR's. Eighty-five patients (77%) are still alive at the time of data collection. This situation is a consequence of the short, variable followup interval. In the course of the study period, a steady number of APR's were performed each year; in contrast, the number of LAR's increased progressively. Table 1 correlates this increase with the more frequent use of the EEA stapler in the last three years of the study. During that period, 50 percent of the LAR's were completed using this device; these 56 anastomoses produced one anastomotic leak and one anastomotic recurrence.

Table 1

USE OF THE EEA STAPLER IN LAR

YEAR	*1978*	*1979*	*1980*	*1981*	*1982*
ALL LAR	12	6	8	16	14
EEA LAR	1	1	4	9	7

UMBERTO CAPUANO, M.D., Surgical Resident, Saint Francis Hospital and Medical Center. DAVID WALTERS, M.D., Assistant Attending, Department of Surgery, Saint Francis Hospital and Medical Center; Clinical Associate in Surgery, Department of Surgery, University of Connecticut School of Medicine, Farmington, CT.

The question now arises regarding the level at which the stapler has proved most useful in the performance of LAR. In Table 2, all cases in the study group are separated by level of the lesion from the anal verge, and several conclusions ensue. First, APR is the procedure of choice for lesions in the lower rectum (0-5 cm.). Second, LAR is the procedure of choice for lesions in the upper rectum (11-16 cm.). Furthermore, the bulk of these anastomoses are sewn rather than stapled because the former technique better accommodates discrepancies in the luminal diameter between the sigmoid colon and the rectum. Third, one-half of the midrectal lesions (6-10 cm.) are still treated with APR (22 APR vs. 20 LAR). Fourth, most of the LAR's in the midrectal region are performed using the EEA stapler. In the 6-8 cm. range, four females and two males were treated with the stapler out of seven total cases. In the 9-10 cm. range, three females and four males were treated with the stapler out of 13 total cases.

Table 2

USE OF APR. LAR. AND EEA vs. LEVEL OF LESION

LEVEL(cm)	*APR(%)*	*LAR(%)*	*(EEA/SEWN)*
0-5	28(53)	2(4)	1/1
6-8	13(24)	7(13)	6/1
9-10	9(17)	13(24)	7/6
11-16	3(6)	31(58)	7/24

Discussion

The treatment of midrectal carcinomas has improved during the course of this study. The technique of LAR has been used more effectively in the resection of midrectal lesions, and this improvement is largely attributable to the use of the EEA stapler. In addition, the anatomical characteristics of the male pelvis did not restrict construction of a low stapled anastomosis. In spite of this trend, however, the overall results are no better than the national average, since one-half of these lesions are still being treated by APR. The routine treatment for lower and upper carcinomas (APR and LAR with a sewn anastomosis, respectively) is consistent with national trends.

As progressively lower anastomoses are attempted, the issue of adequate cancer resection becomes increasingly important. While this study does not address this question, several literature reports confirm that patients undergoing properly performed LAR's have lower complication and operative mortality rates as well as better five-year survival statistics (Table 3). Deddish and Stearns reported on 490 cases of rectal carcinoma in the 6-17 cm. range from the Memorial Hospital.[3] In their study, five-year survival rates were as good or better for both mid-rectal and upper rectal lesions when LAR was used instead of APR. Williams *et al.*, reporting out of Ohio State in 1966, reviewed 182 cases of rectal carcinoma in the 6-15 cm. range; the cases were evenly distributed between APR and LAR.[4] They found a lower complication rate, better operative mortality, and better five-year survival. Their study reported two anastomotic leaks and one anastomotic recurrence. Palumbo and Sharpe, working out of the VA Hospital in Des Moines, Iowa, reviewed a group of 143 cases evenly divided between APR and LAR.[5] They found a comparable complication rate, lower operative mortality, and increased five- and ten-year survival rates. In their experience, there was only one anastomotic recurrence. Slanetz *et al.* retrieved 474 cases at Columbia Presbyterian with equal numbers of APR and LAR in the 8-18 cm. range.[6] They found better five-year survival rates using LAR for both midrectal and upper rectal lesions. Unfortunately, their study was plagued by a 17 percent leak rate and a nine percent anastomotic recurrence rate. Most recently, Pollett and Nichols analyzed 334 cases of rectal carcinoma treated exclusively with LAR.[7] Their population was divided into three groups based on the distal resection margin (less than 2 cm., 2-5 cm., greater than 5 cm.). Overall crude five-year survival rates and cancer specific death rates showed no statistical differences. Margins of less than 2 cm. do not appear to affect survival or local recurrence adversely.

Table 3

LITERATURE SYNOPSIS

	no	*morbidity (%)*	*mortality (%)*	*5-year survival*
Deddish and Stearns				
APR	301	–	2	62/72
LAR	189	–	5	65/78
Williams *et al.*				
APR	93	53	4.3	46
LAR	89	40	2.2	57
Palumbo and Sharpe				
APR	67	38	3.5	50
LAR	76	40	0	57
Slanetz *et al.*				
APR	240	68	5.4	47
LAR	234	56	5.4	57

One final question remains unresolved. Although five-year survival rates were improved by the use of LAR in place of APR, only one study has addressed the five-year *cancer-free* survival rates. In a group of Duke's B and C lesions, Gilbertsen found twenty-one such patients from an initial group of one hundred patients.[8] Only one case had been treated with LAR instead of APR. Data collection at a later date will be necessary to evaluate this question in the context of the present study.

In conclusion, the treatment of midrectal carcinoma is in transition. This study extended the use of LAR in the excision of lesions in the 6-10 cm. range, largely through the use of the EEA stapler. Adequate transfer of the experience gained in larger academic centers to a medical-school affiliated community hospital has occurred in this case.

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Efficacy of Cytology in the Diagnosis of Lung Cancer

NICHOLAS J. MESSINA, III, M.D.

The first large scale study of sputum cytology for the detection of malignant cells was done in 1935. Since that time, cytologic exam of sputa has proven to be effective in the detection and diagnosis of early stages of lung cancer. Hence, the potential usefulness of this technique in finding more curable lesions is obvious.

Methods and Results

During the year October 1, 1982—September 30, 1983, 97 patients underwent cytology screening at St. Joseph Hospital for varied respiratory conditions. Specimens obtained numbered 204 in all. This included 85 bronchial washings, 42 bronchial brushings, 68 sputa, and 9 needle aspirates. Of the 97 patients, 25 new cases of lung cancer were diagnosed. There were 13 women and 12 men; 24 of the 25 had a moderate to heavy smoking history.

Tissue diagnosis was made in 20 of 25 with the remaining five either refusing further work-up or not being subjected to additional procedures because of obvious radiological findings of lung cancer with evidence of diffuse metastatic disease.

Of the 20 patients with tissue confirmation, eight had squamous cell carcinoma, eight adenocarcinoma, three small cell undifferentiated carcinoma and one large cell carcinoma.

In the 15 of 20 patients with histologic diagnosis of cancer, cytology was positive either on bronchial washings, brushings, sputa, aspirate or a combination of the above. Bronchial washings proved to be the most productive modality in this study, yielding 14 positive cytologies. Bronchial brushings yielded three positives, needle aspirate two positives, and sputa one positive.

Correlation between cytologic and tissue diagnosis was good (Figure 2). 100% of squamous cell carcinoma, 50% of adenocarcinoma, 66.6% of small cell carcinoma and 100% of large cell carcinoma were diagnosed by cytology and later confirmed by tissue diagnosis.

Figure 1

	Negative	*Suspicious*	*Positive*	*Unsatisfactory*	*TOTAL*
Bronchial Washing	65	4	14	2	85
Bronchial Brush	30	4	3	5	42
Sputum	58	1	1	8	68
Needle Aspirate	3	2	2	2	9
TOTAL	156	11	20	17	204

Figure 2

	Cytology	*Final Diagnosis*	*%*
Squamous Cell	8	8	100
Adenocarcinoma	4	4	50
Small Cell Undifferentiated	2	3	66.6
Large Cell Carcinoma	1	1	100

NICHOLAS J. MESSINA, III, M.D., Chief Resident, Family Practice, St. Joseph Hospital, Stamford, CT.

Cytology was positive in three cases yielding negative transbronchial biopsies in which subsequent tumor resection revealed tissue diagnosis of carcinoma.

Simple sputum examination in this study was not very rewarding, though it should be noted that many patients only had one specimen obtained prior to bronchoscopy and sputa were collected randomly. There were no false positive diagnoses.

Discussion

The purpose of this study is to assess the accuracy of correlation of cytologic evaluation with histologic tissue specimens in our institution. No effort was made to try to establish the technique which yielded the highest incidence of positive cytologies. Evaluation of each patient was individualized to compare the high correlation between cytologic and tissue diagnosis in the small group with large groups reflected in the literature. Rosa, Prola and Gastow[2] have found positive cytologies in 271 of 381 confirmed cases of lung cancer, yielding a sensitivity of 71%. Other studies disclosed sensitivities from 60 to 90% depending upon the number of samples obtained.

Our experience produced higher yields of positive diagnosis from bronchial washing aspirates than from simple sputum examination. This may be explained, in part, by the random sampling of sputa in our study with collection being carried out at various times of the day, both pre-bronchoscopy and post-bronchoscopy. In several instances, only one specimen was submitted. Best results from sputa examination are reflected from adherence to three or more early morning specimens with yields increasing with implementation of aerosolized induction. Post-bronchoscopy early morning specimens also produce a high yield.[1]

Recently,[4] it has been demonstrated that bronchoalveolar lavage can be of use in the diagnosis of bronchiolo-alveolar cell carcinoma. Since this latter type of carcinoma arises in more distal airways, the recovery of diagnostic cells by this technique might be expected.

The value of cytologic examination of aspiration biopsy specimens has been well demonstrated. Zelch[5] used this technique in 124 cases of carcinoma without a serious complication, and with determination of the specific cell types in 105 of those 124 cases.

Virtually all carcinomas of the lung invade early, and most are unresectable or incurable. The overall survival rate, approximately 10%, might be improved with the early finding of radiographically occult lesions. Although mass screening of patients for lung cancer may not be feasible at present, certain high risk groups including heavy cigarette smokers over the age of 50, those with industrial exposure to nickel, chromium, arsenic, asbestos and uranium, and patients with chronic lung disease may lend themselves to cytologic screening.[3]

The efficacy and accuracy of cytologic examination of tissue specimens from the lung, either by bronchoscopic washing, needle biopsy, brushing or the combination of these has been proven, and yet awaits more widespread application.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Important Advances in Clinical Medicine

Epitomes of Progress—General and Family Practice

The Scientific Board of the California Medical Association presents the following inventory of items of progress in general and family practice. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in general and family practice that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on General and Family Practice of the California Medical Association and the summaries were prepared under its direction.

Chlamydia trachomatis Infections

During the past decade, the importance of *Chlamydia trachomatis* as a human pathogen has become increasingly apparent. Although lacking the notoriety of *Neisseria gonorrhoeae, C trachomatis* is known to produce a similar spectrum of human illness and is now considered a major sexually transmitted pathogen in the United States. In fact, studies indicate that we are currently in the midst of a "*Chlamydia* epidemic."

Chlamydia trachomatis is an obligate, intracellular parasite that has been implicated in a wide spectrum of human infections. Genital chlamydial infections occurring in men include nongonococcal urethritis, epididymitis, lymphogranuloma venereum, proctitis and possibly Reiter's syndrome. In women *C trachomatis* has been implicated as a cause of pelvic inflammatory disease, acute urethral syndrome, mucopurulent cervicitis, bartholinitis, lymphogranuloma venereum, postpartum endometritis and perihepatitis (Fitz-Hugh-Curtis syndrome). Neonatal infections caused by *Chlamydia* include inclusion conjuctivitis and afebrile pneumonia. Finally, the leading cause of preventable blindness in the world, trachoma, is also due to this microorganism.

The most sensitive method of diagnosis remains the tissue-culture isolation of *C trachomatis.* This test, though, is generally available only in laboratories of referral hospitals or large public health departments. Direct cytologic techniques for identifying *Chlamydia*-infected cells lack the sensitivity required for clinical use. Serologic tests are generally not useful in diagnosing current chlamydial genital infections due to a high prevalence of antibody from previous infections; they are of value in diagnosing neonatal chlamydial pneumonia and lymphogranuloma venereum.

As a result of the lack of a convenient, accurate test for diagnosing *C trachomatis,* decisions regarding diagnosis or treatment are frequently made on the basis of the clinical features, the exclusion of other possible pathogens such as gonorrhea and tracing contacts of patients who have nongonococcal urethritis, nongonococcal pelvic inflammatory disease and mucopurulent cervicitis. In view of the estimate that from 10% to 20% of men and 40% of women with gonorrhea are coinfected with *Chlamydia,* consideration should be given to empirically treating these patients with an antibiotic regimen effective against *C trachomatis.* Effective regimens against *Chlamydia* include seven-day courses of tetracycline, 500 mg four times a day, doxycycline, 100 mg twice a day, and erythromycin, 500 mg four times a day.

Martin Quan, M.D.

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Human Insulin

Our ability to artificially synthesize the amino acid sequence of human insulin was first achieved in 1963. Due to the low yield and the impurity of the product, human

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insulin has not been synthesized by this method. Porcine and bovine insulins have been the mainstays of diabetic insulin therapy. A newly developed method of human insulin synthesis has led to licensure and marketing of this product for widespread clinical use.

By artificially splicing the plasmid specifying production of human insulin, *Escherichia coli* can become human insulin "factories." This is one of the first practical applications of recombinant DNA technology. Insulin produced by this method has been immunologically, chemically and physically identical to insulin produced by humans. This recombinant DNA human insulin shows no traces of *E coli* contamination nor of any other side products such as proinsulin.

The major theoretic advantage of human insulin is the diminishment or avoidance of antigenic reactions, both local and systemic. Although less common, the more serious systemic insulin reactions have been associated with clinical situations in which insulin usage has been intermittent and there was a known allergy to other materials such as penicillin. Human insulin (recombinant DNA) is not a panacea and can be antigenic when administered subcutaneously. Nevertheless, this new product should be useful in certain clinical situations.

Family physicians will encounter the need for the intermittent use of insulin in gestational diabetes and during physiologically stressful periods (such as in surgery and the intensive care unit) in cases of type II diabetes. Human insulin may be the first choice in these situations. Cases of newly diagnosed insulin-dependent diabetes may benefit from the use of human insulin, particularly if they have a strong history of multiple allergies. The incidence of lipoatrophy may be diminished. Costs for one vial of insulin at one pharmacy in metropolitan Los Angeles were as follows: human insulin, $18; purified porcine insulin, $11; bovine or porcine insulin, $8. In a recent review, no evidence was found to support the use of human insulin in patients currently using older insulin preparations without allergic reactions.

Wm. MacMillan Rodney, M.D.

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Cost-Effectiveness of Antenatal Rh Factor Immunoprophylaxis

Reducing the severity of Rh factor immunization, once it has occurred, is difficult. More effective by far is preventing the development of Rh factor immunization by administering Rh immune globulin. First licensed for clinical use in North America in 1968, Rh immune globulin injection will probably always prevent Rh factor immunization if given in an adequate dose before Rh factor immunization has taken place. The standard dose for prophylaxis is 300μg. Smaller doses have been almost as effective. In England and Australia, for example, the doses are 100 μg and 125 μg, respectively. However, 300 μg of Rh immune globulin will protect a greater number of women who occasionally have large transplacental hemorrhages.

In 1981 the American College of Obstetricians and Gynecologists reviewed protocols directed at further decreasing the frequency of Rh factor immunization by the use of Rh immune globulin in the following cases: prophylactically during the antepartum period; after amniocentesis; after antepartum hemorrhage and fetal death; after postpartum and postabortional sterilization; after transfusion of platelet concentrates and granulocytes, and in an Rh-negative, unimmunized woman (whether D^u positive or D^u negative) after delivery of an Rh-positive or D^u-positive infant. The most frequent reason for apparent postpartum failure of prophylaxis is most likely Rh factor immunization during pregnancy.

The cost-effectiveness of antepartum prophylaxis remains to be established. Treatment with Rh immune globulin at delivery only is very cost-effective. However, the addition of antenatal treatment where postpartum treatment is already routine is much less cost-effective. Furthermore, it is less cost-effective to limit treatment to women with homozygous Rh-positive husbands than to treat all women or all those with Rh-positive husbands. The possible savings by not treating women with Rh-negative fetuses is outweighed by the added costs of blood typing. Critics have also cited the increased requirements for Rh immune globulin, which may put hyperimmune Rh plasma donors at increased risk, as another disadvantage of antenatal prophylaxis.

There has already been considerable progress in reducing the incidence of Rh immunization. Routine antenatal Rh factor immunoprophylaxis is effective in further decreasing the rate of Rh factor isoimmunization by pregnancy, but greatly increases the demand for Rh immune globulin. It is appropriately done where Rh immune globulin supplies are adequate for all other needs, and cases of erythroblastosis fetalis still occur that might have been prevented by antenatal treatment. If antepartum prophylaxis is used, current recommendations are for the administration of 300μg of Rh immune globulin at 28 weeks' gestation in an unimmunized, Rh-negative woman. Another 300μg dose should be given after delivery of an Rh-positive or D^u-positive baby.

Klea D. Bertakis, M.D., M.P.H.

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Preventing Advanced Colorectal Cancer—Fecal Occult Blood Testing

Recently the American Cancer Society has initiated a three-year educational effort to change the way physicians and the public view the disease of colorectal cancer. The Colorectal Health Check (CHEC) Program will emphasize the expanded use of three standard diagnostic techniques for the early detection of colorectal carcinoma in asymptomatic patients. These techniques consist of testing for occult blood in a stool specimen, rectal examination and sigmoidoscopy.

To obtain a reasonable predictive value, proponents of fecal occult blood testing have recommended certain conditions, which have included the dietary deletion of red meat, vitamin C, peroxidase-rich vegetables and nonsteroidal anti-inflammatory medications. Some have recommended adding a high fiber content to the diet during the test period. Storing stool specimens for longer than four days increases the percentage of false-negatives. Rehydration of slides is no longer recommended because of the increased number of false-positives.

Even with these refinements, there have been critics of stool guaiac screening in asymptomatic patients. The American Cancer Society currently recommends two specimens from each of three separate bowel movements, with adherence to the dietary and storage restrictions. Two studies published in 1983 have reported that most colorectal carcinomas detected by stool guaiac testing were at Dukes' stage A or B. These figures are dramatic deviations from commonly reported prevalences of from 25% to 50% for these prognostically more favorable stages of the disease.

Sontag and co-workers found that 71% of cases of cancer detected by stool guaiac were Dukes' stage A or B. A nonscreened comparison group diagnosed during the same period were found to have advanced (Dukes' C or D) disease in 75% of the cases. Hardcastle and colleagues used a prospective randomized design. In the group accepting fecal occult blood testing, 91% (11 of 12) of cases of diagnosed colorectal carcinoma was diagnosed at stage A or B. In the year following the screening period, ten cases of colorectal carcinoma were diagnosed in the control group. Of these, 60% were stages C and D.

These studies support the American Cancer Society's screening recommendations for fecal occult blood. New developments include vegetable peroxidase inactivators by Helena Laboratories and Coloscreen pads. These may assist clinicians by diminishing the number of false-negatives and improving patient compliance. Available products and their costs have been recently reviewed.

Wm. MacMillan Rodney, M.D.

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Anorexia Nervosa

The *Diagnostic and Statistical Manual of Mental Disorders,* 3rd Edition, (DSM III) includes anorexia nervosa as one of the "eating disorders," along with bulimia, pica, rumination disorder of infancy and atypical eating disorder. Of these, anorexia nervosa has received greatest attention recently in the lay press. It is a disorder that is associated with dysfunction at the physiologic, psychologic, familial and social levels. Recent studies have provided new information on anorexia nervosa; that from family studies is particularly intriguing in regard to the development of treatment regimens.

It is estimated that as many as 1 in 250 young women between the high-risk ages of 12 and 18 years suffer from this disorder. Cases occur in both younger and older women; less than 5% of cases occur in men. Diagnostic criteria for anorexia nervosa include an intense fear of obesity unrelated to actual body habitus, disturbance of body image, weight loss of 25% or more of original or projected weight, refusal or inability to maintain body weight and an obsence of any physical illness that might otherwise account for the symptoms. Most cases occur in women from middle- to upper-class families. Families of affected persons have been described as caricatures of "perfectly normal" families; members may be unaware of chronic emotional withdrawal and isolation. Minuchin and co-workers refer to these families as "psychosomatic families" and describe them as having the characteristics of enmeshment, overprotectiveness, rigidity and an inability to tolerate or resolve conflict. Advocates of family systems approaches comment on the central and regulatory role the anorectic symptoms play in the family.

Treatment of anorexia nervosa is contingent on recognition. Management should be by physicians willing to commit themselves to involvement in a complex, difficult and sometimes frustrating disorder. Clinical approaches must be based on a certainty, shared by clinicians and family members, that weight loss beyond a medically determined level will result in admission to hospital, despite resistances encountered from the patient or her family. Tube feeding, not innocuous, is occasionally required. Physicians must insure that they are not deceived by the ruses of patients. Psychiatrists or family systems-oriented therapists with experience in the management of this disorder should be involved as early as possible. Families and individuals are often strikingly resistant to change; resolving the problem frequently involves uncovering previously denied family pathology and successfully dealing with it. Treatment and support may be required on a long-term basis. Primary care physicians and therapists must communicate openly and regularly; this is especially critical in the early months of care. As gains are made in patient weight and family function, contacts for support may be carefully spaced; physicians must recognize the potential for both early and late recurrence and for the emergency of psychosomatic problems in other family members.

John Blossom, M.D.

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Computer-Assisted Reminders in Primary Care

It is no great surprise that computer-assisted reminders work. That they appear to work better than human memory-assisted systems is also no surprise. How much better and in which ways they have been shown to work may surprise some and interest others.

Computer-assisted appointment reminders reduced the no-show rate from 24% to 14% in a recent study at a university primary care center. Computer-generated reminder letters were cost effective if the no-show rate was above 5%, whereas telephoned or manual letter reminders, both of which cost about twice as much as computer-generated reminder letters, were estimated to be cost effective when the no-show rate was above 11%.

Computer-generated reminders to providers of certain screening, diagnostic and therapeutic maneuvers were more effective in changing the providers' level of compliance with the protocol guidelines than were no reminders. The reminders enhanced preventive care usage twofold in the study group, an important effect because the disparity between intent and action was greater in controls in preventive areas than in diagnostic and therapeutic areas. Computer-assisted physician reminders are more effective in enhancing the level of compliance with accepted intended actions than in initiating new but not yet accepted actions.

Computer-assisted reminders to patients enhance patient compliance with preventive services. Studies of computer-assisted patient reminders of immunizations in children and Papanicolaou smears in adults have shown significant enhancement in compliance with recommended guidelines. These findings are particularly important when one considers that the persons in whom invasive cervical cancer is most likely to develop, for example, are also the least likely to have been adequately screened and more often than not have seen a provider within the screening interval but have not had a Pap test done. The Centers for Disease Control now support the use of reminder systems for immunizations, and the Canadian Task Force supports their use for any "recognized preventive medical procedure."

Computer-assisted reminders have other roles in enhancing compliance, patient education, continuing medical education, quality assurance and research, to mention a few. They can improve patient care as long as that which we remind providers and patients to do is carefully shown to be safe and effective and is accepted before the reminders attempt to change behavior.

T. Warner Hudson, M.D.

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The New Cephalosporins

Most Clinicians familiar with the use of cefazolin sodium would anticipate the development of similar β-lactam compounds. Although many new compounds have been developed, none of them are yet the drug of choice for any disease. Indeed, the third-generation cephalosporin, such as cefoperazone sodium and moxalactam disodium, have less breadth than cefazolin and, generally speaking, are no more effective than the older, cheaper, first-generation compounds. The third-generation drugs are uniquely useful, however, against the group of Gram-negative rods that includes indole-positive *Proteus, Enterobacter, Citrobacter, Acinetobacter, Providencia, Morganella* and *Serratia.* Even among these bacteria, resistance is a problem, especially with *Enterobacter.* The only commonly accepted indications for the new cephalosporins are (1) Gram-negative rod meningitis, (2) rapidly worsening renal failure, (3) Gram-negative rod infections requiring prolonged therapy, (4) Gram-negative rod infections in which greater activity may be useful such as with a foreign body, (5) undrainable abscesses and (6) Gram-negative rod pneumonia. Third-generation cephalosporins have no place in surgery prophylaxis, specific Gram-positive infections (especially staphylococcal), community-acquired pneumonias or outpatient urinary tract infections.

Adverse reactions due to these agents are similar to those in older cephalosporins. Potential problems include emergence of multiple resistances (due to derepression of a gene coding for tightly binding β-lactamase), the development of superinfections (especially by *Candida* and enterococci) and bleeding due to hypoprothrombinemia (correctable with administration of vitamin K, 10 mg per week). One new toxic effect seen with moxalactam and cefoperazone is acute alcohol intolerance due to the inhibition of acetaldehyde dehydrogenase. Cross-reactions in penicillin-allergic patients have not been reported.

None of the new cephalosporins are superior to cefoxitin (a second-generation product) against anaerobic species, and all are much less active than clindamycin or metronidazole.

Cases wherein the third-generation cephalosporins represent a major advance are (1) *Escherichia coli* or *Klebsiella* meningitis (that is, moxalactam and cefotaxime sodium are superior to chloramphenicol or intrathecally given aminoglycosides), (2) second-line treatment of penicillinase-producing *Neisseria gonorrhoeae* infections and (3) nonneutropenic bacteremia in patients in whom resistance is a problem and *Pseudomonas* is not a consideration.

M. Scott Willson, M.D., M.P.H.

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AIDS—A New Epidemic

Acquired immune deficiency syndrome (AIDS) is a disease characterized by the occurrence of unusual neoplasms, chiefly Kaposi's sarcoma, and opportunistic infections, usually *Pneumocystis carinii* pneumonia. It was first recognized in June 1981 in six previously healthy homosexual men, and by April 1984 some 3,954 cases had been reported to the Centers for Disease Control, affecting homosexual men, intravenous drug abusers and Haitians both in and outside Haiti. Other groups affected include persons with hemophilia and other transfusion recipients, female sexual partners of men with the disease and infants from high-risk households. The ultimate mortality is unknown, but may approach 100%.

AIDS is defined empirically as the occurrence of infections and malignant lesions characteristic of an immunologic deficiency in the absence of any other cause of immunodeficiency. Basic science and clinical study of the disease has been hampered by the lack of a specific diagnostic marker. The classic syndrome commonly begins with *P carinii* pneumonia manifested by cough, chest discomfort and mild fever for two to ten weeks, accompanied by weight loss and diarrhea with or without enteric pathogens. Oral *Candida,* primary or recurrent herpes simplex and disseminated cytomegalovirus and Epstein-Barr viruses are frequently seen. Other opportunistic infections may also be found.

Two types of malignancy are seen with AIDS: Kaposi's sarcoma occurs in about 35% of patients, is commonly disseminated and usually presents as blue or brown nodules or plaques, usually on the legs; Burkitt's or immunoblastic lymphomas occur less frequently.

In addition, there is a syndrome of chronic lymphadenopathy, defined as three months' duration involving two or more extrainguinal sites with reactive hyperplasia on the lymph node biopsy specimen in the absence of illness or drugs that might cause lymphadenopathy. It is not clear if this represents a prodrome of AIDS or an entirely different syndrome, but in many who have it, classic AIDS develops.

Lymphopenia may be present, and T-cell subset analysis shows a decreased helper-suppressor cell ratio. Additionally, there is polyclonal B-cell activation with increased levels of serum immunoglobulin and abnormalities in the serologic response to a new antigen.

The cause of AIDS is yet unknown, but epidemiologic data suggest a single agent transmitted in a manner like hepatitis B, with an incubation period of about 18 months. Recent virologic and immunologic studies have shown the presence of human T lymphotrophic retroviruses (HTLV III) in a large percentage of those who have AIDS. Further studies are needed before causality can be determined or an immunization developed.

AIDS is clearly spread by sexual contact and via bloodborne transmission. There is no evidence that it is transmitted through casual contact. It appears to be concentrated in the United States, largely in major cities on both coasts, but is also seen in Europe, Haiti and Africa. The number of new cases is doubling every six months, and though about 3% of cases belong to a no-known-risk group, it is unknown whether the epidemic will extend into the general population.

Neil Joyce, M.D.

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Premenstrual Syndrome

Premenstrual syndrome has become a popular topic in the lay press over the past few years, and it also has a growing medical literature. Because it is common (20% of women of childbearing age) and because treatment relies heavily on a good doctor-patient relationship, this disorder is well suited for treatment by a family practitioner.

Premenstrual syndrome is defined as an array of somatic and psychologic symptoms that occur during the luteal phase of the menstrual cycle and disappear sometime during menses. The symptoms are variable in occurrence and severity, but are significant enough to cause temporary incapacitation.

Common somatic symptoms are bloating, breast pain or tenderness, edema, skin rashes, hot flushes, headache, pelvic pain and change in bowel habits. Common psychological symptoms are irritability, aggression, tension, anxiety, depression, lethargy, insomnia, change in appetite, crying, change in libido, thirst, loss of concentration and poor coordination.

Diagnosing the disorder is dependent on a careful history. A diary of somatic and psychological symptoms during the menstrual cycle is essential for careful diagnosis. Three common patterns of symptoms occur. Some patients have problems during the week before menstruation whereas others become symptomatic starting at ovulation and are affected for two weeks. Others experience a few days of symptoms at the time of ovulation, with recurrence during the week before the menses. The symptoms generally disappear by the second day of menses.

Patient education and reassurance are the most important aspects of therapy. Many women find relief with an understanding of the condition and with reassurance that they are not suffering from a mental illness. General measures that may be helpful are regular exercise and a low-salt, low-carbohydrate (especially simple sugars), high-protein diet. Discontinuation of nicotine and caffeine is also advisable.

Pyridoxine hydrochloride (vitamin B_6) in dosages of 200 mg to 800 mg daily is generally the first choice of drug therapy for this condition and is often effective. Dosages in this range are safe, and patients should be counseled to avoid higher doses that might cause a peripheral neuropathy. Spironolactone, 25 mg two to four times a day, has recently gained in popularity, especially in women with significant edema. Progesterone suppositories, 200 mg to 400 mg twice a day (may be used vaginally or rectally) beginning 10 to 14 days before menses, is a popular form of treatment. The Food and Drug Administration has not approved progesterone for treatment of this disorder and the cost is about $1 to $2 per suppository. Since no pharmaceutical manufacturers in the United States produce this suppository, physicians must find a pharmacy that is willing to formulate them. Taking synthetic progestins by mouth has not been effective and may actually make the symptoms worse.

Kenneth W. Patric, M.D.,
Joseph E. Scherger, M.D.

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Outpatient Management of Diabetes

Recent developments in the treatment of diabetes mellitus have dramatically improved the ability of primary care physicians to manage these patients. Although conflicting opinions still exist regarding whether or not tight control of blood glucose diminishes the risk of the microvascular complications of diabetes developing, most authorities believe that the available data suggest that patients and physicians should strive for the tightest control possible, without subjecting a patient to hypoglycemia. Ideally, we should strive in nonpregnant patients for fasting blood glucose levels of 140 mg per dl or below, and postprandial levels below 200 mg per dl. Aso, the glycosylated hemoglobin level – a widely available test that reflects a patient's glucose control over a period of several weeks – should be kept as close to normal as possible.

Over the past years the dietary recommendations for persons who have diabetes have changed. Weight reduction is stressed for those who are overweight and is the first line of therapy for those with type II (noninsulin-dependent) diabetes. Complex carbohydrates are not restricted; in fact, they may constitute up to 60% of the daily caloric intake. Cholesterol, saturated fat and sodium intake should be reduced. Increasing intake of dietary fiber also improves glucose control.

Outpatient monitoring of glucose is changing dramatically. Recent studies have shown a very poor correlation between urine glucose and blood glucose levels. Home blood glucose monitoring using reagent strips with or without reflectance meters, is much more accurate and is gaining acceptance. Automated lancets have removed much of the discomfort of bloodletting.

Although some controversy about the oral hypoglycemic agents still exists, few believe that their risks are as great as suggested by the University Group Diabetes Program data. Nonetheless, oral agents are used only in cases of type II diabetes when diet alone has failed and, if possible, are avoided in patients with cardiac, hepatic or renal disease.

New, highly purified insulins are available, including human insulin of recombinant DNA origin. Patients with insulin-dependent diabetes currently doing well with the older products need not be switched. Patients beginning insulin therapy, however, might do well to start with human insulin or a highly purified porcine insulin – in theory, diminishing the risk of future allergic complications.

Finally, intensive regimens consisting of multiple subcutaneous injections a day or continuous insulin pump infusion will provide better glucose control than conventional regimens and should be considered for all cases of type I (insulin-dependent) diabetes. Although some deaths have been attributed to the use of the insulin pump, the death rate is not greater than the age-specific death rate for this population.

William A. Norcross, M.D.

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Precursors to Malignant Melanoma

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The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

The incidence of melanoma and the number of deaths from it are increasing in many areas of the world. There is evidence that early recognition and surgical removal of melanoma makes this a highly curable cancer. In recent years, medical scientists have become aware of a possible association between certain preexisting pigmented skin lesions and cutaneous melanoma. This interest has developed from identification of two suspected precursors to cutaneous melanoma: (1) acquired abnormal moles known as dysplastic nevi, present both in the general population and in certain melanoma-prone families, and (2) certain congenital nevi. Identification and appropriate management of such precursors could significantly reduce the incidence of and mortality from melanoma.

In an effort to resolve some of the questions surrounding these issues, the National Institutes of Health convened a Consensus Development Conference on Precursors to Malignant Melanoma on October 24-26, 1983. After a day and a half of presentation by experts of data on these two types of lesions and their potential for becoming cancerous, a consensus panel including representatives of dermatology, pathology, oncology, family medicine, immunology, epidemiology, and the general public considered the scientific evidence and agreed on answers to the following key questions:

1. Can dysplastic nevi and congenital nevi be defined clinically and histologically?
2. Are these nevi precursors to melanoma? What are the prevalence, natural history, and determinants of these precursors?
3. What is appropriate management of patients with dysplastic nevi and congenital nevi regarding: diagnosis, treatment, followup, familial screening, and education?
4. What directions should be taken for future research on precursor lesions to melanoma?

Conclusions

This conference highlighted an important advance in our understanding of melanoma through the identification of a familial syndrome in which multiple dysplastic nevi are associated with development of melanomas. The investigation of patients with this syndrome affords an opportunity not only to advance our knowledge of the biology of melanoma but also to aid the identification of treatable precursor lesions and early melanomas. The result may be a reduction in mortality in these patients.

The consensus panel found that melanoma may arise *de novo* as well as in association with preexisting melanocytic nevi. The panel also agreed that the dysplastic nevus, a distinctive lesion both clinically and histologically, has been identified in this context, particularly in melanoma-prone families. Dysplastic nevi are both markers and precursors for familial melanoma. Melanoma may develop also in congenital nevi, especially when the lesion is larger than 20 cm.

Strategies for treatment and followup should be formulated individually, on the basis of the risk of melanoma to each patient. Patients with dysplastic nevi and a family history of melanoma should be followed frequently, with documentation of lesions and excision

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

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of changing nevi. The relatives of patients with melanomas should be examined for dysplastic nevi and melanoma in view of the familial aggregation of both lesions. Patients with congenital nevi should be followed periodically for changes. Need for education in examination of lesions by patients, relatives, and health professionals is emphasized.

The paucity of existing information on precursors of melanoma coupled with its increasing incidence indicate a continuing need for research.

1. Can dysplastic nevi and congenital nevi be defined clinically and histologically?

Dysplastic Nevi

Dysplastic nevi are acquired pigmented lesions of the skin whose clinical and histologic definitions are evolving. They differ from common, acquired pigmented nevi in several respects and some cannot be clinically distinguished from melanoma. They were first recognized because of their unusual appearance and increased frequency in certain families. The features of dysplastic nevi that occur in affected families do not differ from those of sporadic lesions.

Typical dysplastic nevi measure 5 to 12 mm in diameter and tend to be larger than common nevi. Dysplastic nevi have both macular and papular components and have borders that usually are irregular and frequently are ill-defined. Their color is variegated, ranging from tan to dark brown on a pink background. Dysplastic nevi may appear anywhere on the body, especially on the trunk. Their frequent occurrence on covered areas, such as buttocks, breast, and scalp, represents a distribution different from that of common nevi. Young adults reportedly have an average of 25 common nevi, but an individual with dysplastic nevi may have more than 100 lesions. Although common nevi usually have appeared by young adult life, dysplastic nevi usually begin to appear in adolescence and continue to appear even after the age of 35.

The accurate diagnosis of dysplastic nevus depends upon histologic confirmation. Typical histopathologic features are superimposed on those of a junctional or compound nevus and include:

1. Basilar melanocytic hyperplasia with elongation of rete ridges.
2. Cytologic atypia with enlarged hyperchromatic melanocytic nuclei, often present but not essential for the diagnosis.
3. Melanocytes, spindle-shaped and arranged horizontally, or occasionally epithelioid, aggregating in nests of variable size and fusing with adjacent rete ridges to produce bridging.
4. Lamellar and concentric dermal fibroplasia.
5. Lymphocytes in patchy or diffuse superficial dermal infiltrate.

These changes may appear focally in any given lesion and may not be evident unless multiple histopathologic sections are studied. These microscopic findings of dysplastic nevus are distinct from those of malignant melanoma *in situ.*

Congenital Nevi

A congenital nevus is a melanocytic nevus that is present at birth. Some lesions first become apparent during infancy, and when they do, it is assumed that preexisting nevus cells were present. This assumption is based on clinical, histopathological, and biological data. Not all pigmented lesions present at birth represent melanocytic nevi.

Congenital nevi have been divided into three groups according to size in infancy:

1. Small (less than 1.5 cm in diameter).
2. Medium (1.5 to 20 cm in diameter).
3. Large (greater than 20 cm in diameter).

It is recognized that nevi thus classified by size occupy different proportions of the body surface at different ages. The sizes of the lesions have different implications for diagnosis, treatment, and prognosis.

Large congenital nevi vary greatly in size. Some occupy a major portion of the body surface and are called giant congenital nevi, bathing trunk nevi, or garment nevi. Clinical features of these lesions are easily recognized and consist of:

1. Grossly irregular surface.
2. Increased pigmentation, with varying shades of brown.
3. Hypertrichosis.

These features are present variably within a given lesion and from patient to patient. Although present at birth, the full extent of the large congenital nevus may not become evident until later in infancy.

Medium-sized lesions share the above clinical features and are almost always easily identified as congenital nevi. They are usually apparent at birth but, again, some appear in infancy.

Small congenital nevi may not be recognized as such if the lesions are not apparent at birth. Clinical features may not differ from those of acquired melanocytic nevi because these smaller lesions may have a smooth surface, have more uniform pigmentation, and lack hair.

The classic microscopic description of congenital nevi includes nevus cells in the following locations:

1. The lower two-thirds of the dermis, occasionally extending into the subcutis.
2. Between collagen bundles distributed as single cells, or cells in single-file, or both.
3. In the lower two-thirds of the reticular dermis or subcutis, associated with the appendages, nerves, and vessels.

Some congenital nevi do not have these microscopic features. Large congenital nevi usually do in some areas, but elsewhere they may be indistinguishable from acquired nevi. Medium-sized congenital nevi may or may not show the classic microscopic features. Small congenital nevi often do not show the classic microscopic features and thus may be indistinguishable from acquired nevi. On occasion, the classic microscopic picture of congenital nevus may be seen in an acquired nevus.

2. Are these nevi precursors to melanoma? What are the prevalence, natural history, and determinants of these precursors?

Melanomas may arise *de novo* or in association with preexisting melanocytic nevi. These preexisting lesions include dysplastic nevi, congenital nevi, and common acquired nevi.

Dysplastic Nevi

Evidence suggests that melanomas can arise directly from dysplastic nevi. Because the reported prevalence of individuals with dysplastic nevi is in the range of 2 to 8 percent, the impact of dysplastic nevi on the incidence of melanoma may be considerable.

Dysplastic nevi can be inherited or may be sporadic. Familial dysplastic nevi can be inherited as an autosomal dominant trait. Sporadic lesions are those occurring with no dysplastic nevi detected in family members. The presence of multiple dysplastic nevi in two or more family members has been termed the "dysplastic nevus syndrome."

Among caucasians in the United States, the lifetime risk of developing cutaneous melanoma is about 0.6 percent or 1 in 150; the risk is about one-tenth of this among black Americans. Among patients with dysplastic nevi, who constitute a heterogeneous group, the overall lifetime risk has been estimated at 10 percent. The risk is greater for those having one relative with melanoma than for those with no such relative.

The lifetime risk of melanoma may approach 100 percent for those people with dysplastic nevi who are from melanoma-prone families, i.e., families with two or more first-degree relatives having cutaneous melanomas. Melanomas in people from these families may arise within the dysplastic nevi or *de novo*in ostensibly normal skin.

Congenital Nevi

Congenital nevi occur in approximately 1 percent of all newborns. Most of these nevi are small, as defined above.

The lifetime risk of melanoma in patients with large congenital nevi has been estimated to be 5 to 20 percent. It is unclear to what extent melanoma develops in smaller congenital nevi; the incidence has been reported to be increased, but the magnitude of that increase is not well established.

3. What is appropriate management of patients with "dysplastic" nevi and congenital nevi regarding: diagnosis, treatment, followup, familial screening, and education?

Dysplastic Nevi

The formulation of an effective management strategy for patients with dysplastic nevi depends upon their classification in one of two groups:

1. Dysplastic nevi *with* a family history of melanoma.
2. Dysplastic nevi *without* a family history of melanoma.

This classification requires an accurate family history and evaluation of first-degree relatives.

Diagnosis

A patient who is suspected of having one or more dysplastic nevi should have the entire integument examined closely in good light. This should include a careful examination of the scalp and eyes. At least one of the more atypical-appearing dysplastic nevi should be subjected to excisional biopsy. The family history should be obtained with special attention given to such items as "moles," "skin conditions," "skin cancer," and melanoma.

Familial Screening

If the family history suggests melanoma, an effort should be made to examine all first-degree relatives. If a melanoma is found in any of these family members, all blood relatives should be examined to determine the extent of the risk of melanoma in the kindred.

Treatment and Followup

In patients with dysplastic nevi and any family history of melanoma, the indication for excising additional dysplastic nevi is the suspicion of early melanoma. In such lesions, the decision will be influenced by variation in color, size of the lesion relative to the patient's other nevi, or progression. Followup should be conducted every 3 to 6 months. In this and all instances where close followup of dysplastic nevi is indicated, photography may be helpful to document the appearance of lesions.

In patients with dysplastic nevi and no family history of melanoma, the risk of melanoma is uncertain. Extant lesions should be followed for evidence of progression.

Education

All patients with dysplastic nevi should be educated about their need for followup. They should be taught self-examination to detect changes in existing nevi and the emergence of new nevi. Finally, as with other people at risk for melanoma, they would be prudent to avoid excessive sun exposure and use sun screens.

Congenital Nevi

The management of congenital nevi depends primarily on their size and the perceived risk of development of melanoma. Large congenital nevi are rare, and their management is complex. The management of patients with large congenital nevi should be individualized to accommodate such factors as technical difficulty and cosmetic consequences of surgical removal as well as the risk of melanoma. Because of the unknown magnitude of the increased incidence of melanoma arising in other congenital nevi, a conservative management is recommended. The lesions should be periodically documented, measured, and observed for alterations of size, shape, color, and topography.

There are insufficient data at present to recommend prophylactic excision of all congenital nevi. Patients with congenital nevi should be examined periodically, initially by their parents, and then be taught self-examination. If an alteration in the nevus is detected, it should be evaluated by a physician and biopsied, if appropriate.

4. What directions should be taken for future research on precursor lesions to melanoma?

The paucity of existing information on precursors of melanoma coupled with the increasing incidence of melanoma suggests a need for more research. Epidemiological, clinical, and laboratory studies are required of populations known to be at increased risk for melanoma as well as of general populations.

Prospective studies are needed to collect data aimed at:

1. Determining patterns of inheritance in melanoma.
2. Improving the accuracy and reproducibility of diagnosis.
3. Establishing the incidence and prevalence of melanoma associated with each specific precursor lesion.
4. Describing the natural history of these precursors.
5. Identifying other potential risk factors for melanoma.
6. Quantifying the incidence, if any, of excess non-melanocytic neoplasms in these patients.

Pilot studies should be initiated to evaluate the feasibility of and methodology for large-scale prospective studies. The feasibility and effectiveness of proposed interventions also should be determined.

Laboratory studies should be directed toward understanding how pigment cells in precursor lesions undergo transformation. Research efforts might include:

1. The application of techniques in cell and organ cultures to characterize the pigment cells from various types of nevi.
2. A search for specific markers of normal and transformed melanocytes.
3. Identification of possible oncogenes for melanoma.
4. An attempt to understand how melanocytes interact with both humoral and cellular immunologic processes.
5. Studies of systemic abnormalities in patients with dysplastic nevus syndrome.

Members of the Consensus Development Panel were: Ruth K. Freinkel, M.D., (Chair) Chicago; Gary W. Cage, M.D., Bethesda, MD; William A. Caro, M.D., Chicago; D. Martin Carter, M.D., Ph.D., New York; Philip Cole, M.D., D.P.H., Birmingham, AL; Robert C. Elston, Ph.D., New Orleans; Robert G. Freeman, M.D., Dallas; Hank C. George, FALU, Milwaukee; Aaron B. Lerner, M.D., Ph.D., New Haven, CT; Daniel K. Onion, M.D., M.P.H., Augusta, ME; Irene Pollin, M.S.W., Chevy Chase, MD; Thomas T. Provost, M.D., Baltimore, MD; Maria L. Turner, M.D., Washington, D.C.; William C. Wood, M.D., Boston, MA.

Members of the Planning Committee were the following: Rosemary Yancik, Ph.D., Bethesda, MD; Ruth K. Freinkel, M.D., Chicago, IL; Mark H. Greene, M.D., Bethesda, MD; John T. Headington, M.D., Ann Arbor, MI; Stephen I. Katz, M.D., Bethesda, MD; Martin C. Mihm, Jr., M.D., Boston, MA; Fitzhugh Mullan, M.D., Bethesda, MD; Elliott H. Stonehill, Ph.D., Bethesda, MD; Jerome W. Yates, M.D., Bethesda, MD.

The conference was sponsored by the following: National Cancer Institute, Vincent T. DeVita, Jr., M.D., Director; Office of Medical Applications of Research, J. Richard Crout, M.D., Director.

Managed Health Systems: A Boon or Bane for Physicians?

MICHAEL E. HERBERT

One of Paul Starr's themes in his book *The Social Transformation of American Medicine* is that physicians in America today are in danger of losing the preeminence and control over the practice of medicine which most of them, including physicians in Connecticut, have enjoyed over the course of their professional careers. This article will examine this theme in light of some recent trends in health care delivery, both nationally and here in Connecticut. It is my contention that the danger of loss of physician control which Starr describes is real. But it is certainly not inevitable, although physicians must get themselves organized and avoid certain pitfalls or else they will surely lose that control.

My experience in the health care field only extends back to 1970, not nearly as extensive as most Connecticut physicians, but during those past 14 years I have seen major changes occur which are frightening to me, and would be even more so if I were, as most Connecticut physicians are, practicing fee-for-service medicine either by myself or with a partner or a few other partners of the same specialty.

Let's examine a few trends in health care delivery, and, as we do, pay special attention to two particular points: (1) the almost-whirlwind speed at which these events are taking place in the health care delivery world today; and (2) how seldom I mention the word "physician" as either an instigator or controller of these profound changes.

1. Health care delivery is increasingly being dominated by large corporate firms.

In the HMO industry, for example, there are currently 14 major chains in the U.S., representing both for-profit and non-profit HMOs, who operate HMOs in more than one state. Some of these HMOs have expanded their operations by more than 100% recently and already comprise 73% of total HMO enrollment in this country. In Philadelphia over the past 18 months, four of the nine HMOs have been taken over by national firms. Hospital chains now run one-third of the hospitals in this country, up from 12% a decade ago, and it is estimated that by 1990, 90% of the nation's hospitals will have chosen partners. In just the past three years, 27 investor-owned and 229 non-profit hospital systems added more than 400 hospitals to their networks. In the nursing home field, Beverly Enterprises now owns nearly 700 nursing homes, with revenues in excess of $1 billion per year.

2. These large firms are predominately insurers and large investors, with a major shift from non-profit to investor-owned, for-profit firms.

A few years ago, there were virtually no for-profit HMO firms. Now, over one-quarter of all HMOs are for-profit, and many of the remaining 220-odd HMOs are considering a conversion to a for-profit status for a very elementary reason: HMOs are currently the darlings of Wall Street—trading at 20 to 40 times earnings, and are raising millions of dollars in capital through the public market.

In 1983, five national HMO companies went to the public market and raised a total of almost $85 million and created a total market value, at the offering prices, of over $560 million. If you add the nine public debt offerings by HMOs through the bond market, you come up with $480 million in capital raised in the past year and a half by less than a dozen and a half HMOs—which is over $100 million more than the $375 million paid out by the federal government to all of its HMO grantees throughout the 1970's.

3. Health care delivery is increasingly being built around larger and larger physician groups, whether these groups are prepaid or not.

At the same time, the solo practitioners and small, single-specialty groups such as we have traditionally had throughout the state of Connecticut are becoming more and more the exception rather than the norm. A few Connecticut physicians may remember that in 1940 only 1.2% of all physicians practiced with someone else. In 1975, 54% of M.D.s were solo practitioners and 17% were in practices of 5 or more M.D.s, but by last year, only 49% of M.D.s were in solo practice and 23% were in practices of 5 or more. Also, the

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MICHAEL E. HERBERT, President, Physicians Health Services, Trumbull, CT.

number of two-person groups declined while the number of three-and four-person groups increased.

4. The health care industry is experiencing rapid vertical integration.

This simply means that insurers are becoming providers, hospitals are offering free-standing ambulatory care, or home care, or their own health plans. And this trend is being helped along by the much- publicized glut of physicians and the inherent competitive advantages of competing health plans such as HMOs and Preferred Provider Organizations, or PPOs. The federal government estimates that in 1980 there were 197 doctors for every 100,000 people in the U.S.; that number will rise to 243 by 1990 and to 271 by 2000. In 1990, it is estimated that the country will have 63,000 more physicians than it needs. Denver already has one doctor for every 210 people; San Francisco, one doctor for every 160 people.

5. Health care delivery points are being increasingly decentralized.

Besides seeing the free-standing surgery centers, or surgicenters, we are also seeing the "Docs in a Box," or urgicenters which, of course, started only a few years ago in Rhode Island, and now are appearing all over our state. We now have three in the greater Bridgeport area and several more in New Haven County. We are seeing physicians opening multiple offices and returning to evening and weekend hours, and we are even seeing SEARS begin to market the traditional physician's "black bag" to consumers.

6. The payment system for health care delivery is becoming "Pay as You Like."

In other words, companies are offering their employees more and more choices such as a high-option plan, a low-option plan, a staff-model HMO such as Kaiser, an IPA/HMO, and a PPO. In communities like the Twin Cities in Minnesota, San Francisco and Boston, it is not uncommon for an employer to be offering five or six HMOs in addition to the company's health insurance plan. It's becoming an employee's smorgasbord and a benefit manager's nightmare.

7. All of these trends are occurring much sooner than ever before.

It's Alvin Toffler's *Future Shock* arriving in health care in George Orwell's *1984.* Why so much faster? For several reasons.

(a) Insurers now finally recognize that health care costs must be brought under control. And they're doing something about it. Two of the largest providers of care in the HMO industry, for instance, are now commercial insurance companies. CIGNA, the merged insurance giant (Connecticut General and INA) operates HMOs in 10 cities with over 700,000 enrollees, and Prudential Insurance Company now operates HMOs in 11 cities with over 300,000 enrollees.

(b) PPOs are growing rapidly in other parts of the country and are being considered seriously by many hospitals right here in Connecticut. About 100 PPOs were formed in California last year, and many of these are now operational. Nationwide, it is estimated that there are already 600 PPOs either planned, developing, or operational.

(c) Public programs (Medicare and Medicaid)intend to force the issue by contracting only with selected providers, throwing freedom of choice to the winds in an effort to halt escalating costs. Medicare now has 57 demonstration projects all over the country where the Medicare enrollee agrees to surrender freedom of choice in return for better coverage at a more reasonable price.

(d) The new national firms I alluded to earlier are displaying a real aggressiveness in an attempt to increase their market share.

For instance, U.S. Health Care Systems, the first HMO to go public over a year ago, is now the country's largest IPA/HMO with over 260,000 members. Until 1982, the company operated only in the Philadelphia area, but last March it expanded to central and south Jersey. Management has recently opened another HMO in Jacksonville, Florida, and is expanding again—to Orlando. Some time during the year, the New Jersey plan which has already become the state's largest HMO will probably expand its area of operation to include the counties that border on metropolitan New York City. Beyond 1984, expansion to additional service areas also seems assured. Management has identified about two dozen additional population centers they believe capable of supporting a new IPA/HMO.

A Minneapolis-based IPA/HMO, Physicians Health Plan, is managed by an HMO management company which now runs HMOs in seven states, including a statewide IPA/HMO in Rhode Island, and has just opened a Manhattan office to handle its East Coast expansion.

(e) Employers are initiating a veritable revolution in benefits by restructuring them to encourage more employee cost-sharing, and some incredible efforts are being made by employers to get their employees to join HMOs. Witness:

Philip Caldwell, Ford Motor Company Board Chairman, in an unprecedented move for Ford, sent a personal letter to each Ford employee asking him or her to consider seriously the option of joining an HMO. Although only 9% of Ford's 275,000 employees belong to HMOs, the company saved over $7 million on those employees who did join HMOs. Ford, by the way, did this because from 1979 to 1983 it had a $200,000 increase in health care costs, even though it had 180,000 fewer employees in 1983 than it had in 1979.

> Chrysler Corporation, which estimates that $600 of the cost of each of its new cars goes to pay for its employees' health care or $6,000 per year per active employee, offered a $250 savings bond last year to each of its employees who convinced a fellow employee to sign-up for an HMO option.
>
> Lockheed Corporation, a 70,000 employee Fortune 500 company, has just instituted a new policy whereby all new Lockheed hires are being offered *only* HMO coverage for their first year of employment. This is being done because the company is convinced that after employees experience one year with the broad coverage an HMO offers that the employee won't want to switch to the health insurance option.

Now, let's move closer to home and see what some of these powerful changes are bringing about right here in Connecticut. United Technologies, the largest employer in New England, last fall spent $75,000 to promote HMOs here in Connecticut to their employees at Pratt & Whitney, Sikorsky, Norden and Hamilton Standard. This was not done as simply a good will gesture to U.T.C. employees. It was done primarily for a bald-faced, bottom-line reason: The company was saving premium dollars, about $20 per family per month, on every employee who elected the HMO options over the company's alternative coverage with Connecticut General.

The Kaiser Foundation Health Plan, the largest HMO chain in America with nearly 5 million enrollees, expanded into New England two years ago by acquiring the North Central Community Health Plan, a struggling staff-model HMO in the greater Hartford area. And this summer Kaiser announced that it was acquiring the Westchester Community Health Plan, a staff-model HMO in the White Plains area, for the express purpose of establishing their presence in the Westchester County-Fairfield County market.

And then there's Blue Cross and Blue Shield of Connecticut (BC/BS). Most Connecticut physicians are aware that Blue Cross and Blue Shield finally last year stopped paying for non-emergent use of the emergency room. But physicians may not at all be aware that the Blues in this state have now adopted an aggressive posture to assume dominance of our state's HMO industry. To do this, they have formed a new corporation called "Prepaid Health Plans of Connecticut," in conjunction with CHCP, the staff-model HMO in Long Wharf in New Haven, to expand staff-model HMOs into state markets not currently served by HMOs. In a recent news article, John Nelsen, President of Prepaid Health Plans, was quoted as saying: "Among the 'primary target' markets (for this staff-model HMO expansion) are the corporate centers of Stamford, Norwalk, and Danbury, the industrial city of Waterbury, and the eastern Connecticut cities of Norwich and New London."

Blue Cross and Blue Shield is also attempting to assume dominance of the IPA part of the HMO industry here in Connecticut, and in so doing is marketing the concept of "freedom of choice" which, to BC/BS, means:

1. Freedom to choose a BC/BS health insurance package;
2. Freedom to choose a BC/BS staff-model HMO (central facility, salaried physicians); or
3. Freedom to choose a Blue Cross IPA/HMO.

That's not freedom of choice; that's no choice at all, a *monopoly.* That's a strong statement, one the Blues themselves will undoubtedly vigorously dispute. And so be it. This issue is of paramount concern to all Connecticut physicians and must be joined.

Managed health systems such as health maintenance organizations are thriving here in Connecticut just as they are in the rest of the country. Physicians in all parts of the state are now being actively recruited to associate with these managed systems of care. Many physicians may feel they can turn a deaf ear to these managed health systems, but my premise is this: physicians can no longer afford to go it alone because they must be able to deliver their product, traditional fee-for-service medicine, to the public in a manner that will make that product competitive with what these managed health systems have developed and are offering to the public.

Physicians who choose to ignore these systems should consider that the climate for HMO development in 1984 is better than it ever was in the late seventies or even just a couple of years ago for the following reasons:

(a) Price parity—HMOs now cost less or the same as health insurance, rather than considerably more; this is due to several years of double-digit health insurance premium increases while HMO premiums have been increasing at a lesser rate;

(b) Most HMOs have much greater management and capital resources at their disposal to help promote the product;

(c) Corporate and public awareness of HMOs is vastly greater than it was only a few years ago, even in areas where no HMO exists . . . we live in a transient society that has moved around and been exposed, favorably I might add, to HMOs all over the country.

(d) All levels of government are now actively promoting HMOs. Here in Connecticut, for instance, the state is actively promoting HMO enrollment among its state employees. And the municipalities in Connecticut several years ago discovered HMOs. The state's largest city, Bridgeport, now has over half of its employees enrolled in Physicians Health Services (PHS), an IPA/HMO.

And, of course, I have already touched on the federal government's active support of HMOs. A recent report entitled "10 Year Report" on the HMO industry was actively supported by the federal government which also recently published an "Investors Guide to Health Maintenance Organizations" designed expressly to get Wall Street actively interested in and supportive of HMOs. Now that's really an interesting marriage of big government and big business.

(e) And lastly, the climate is much better for HMOs in 1984 than it was a few years ago because physicians are now actively and openly endorsing the HMO concept.

The table below shows how Connecticut HMOs have increased in number and size over the past nine years, with almost all of this enrollment concentrated around the three population centers of Bridgeport, New Haven and Hartford. Recent or planned HMO expansions into new areas such as New London and Windham Counties, Danbury and Stamford will increase the rapid HMO enrollment growth we have already seen. It is not at all unreasonable to assume that half of the population of Connecticut will be enrolled in managed health systems by the end of this decade.

Physicians must, therefore, get in touch with the times, get organized, and, most importantly, consider carefully which of the managed health care systems can best preserve the best of what traditional medicine has always had to offer.

CONNECTICUT HMO ENROLLMENT

	1975	*1980*	*1983*	*1984**
Community Health Care Plan (Staff)	16,389	26,074	33,250	38,000
Connecticut Health Plan (Staff)	–	8,023	10,000	9,800
Connecticare (IPA)	–	–	3,350	10,500
Constitution Health Network (IPA)	–	–	–	8,000
HealthCare, Inc. (IPA)	–	1,568	6,000	14,000
Kaiser Foundation Health Plan (Group)	–	4,951	17,200	22,700
Physicians Health Services (IPA)	–	8,278	29,000	42,000
Southern CT. Community Health Plan (Staff)	–	3,857	–	–
Yale Health Plan (Staff)	20,064	22,715	23,650	23,800
TOTAL	36,453	75,466	122,450	168,800

*Estimated

The majority of physicians in all of Fairfield County (except greater Danbury), in the lower Naugatuck valley area, and in New London County have elected to associate with Physicians Health Services (PHS), the state's largest and most financially successful HMO. PHS is the only HMO in the state which has a statutory requirement in its by-laws that a majority of its Board of Trustees be physicians and that its Board Chairman also be a physician. PHS's current enrollment of 42,000 members is fully one-quarter of the entire state's HMO enrollment, and exceeds the total enrollment of the state's other three IPA/HMOs. Most importantly, PHS's Board of Trustees voted last fall to expand throughout the state of Connecticut wherever it appeared that other managed health systems which might not be in the physicians' best interests were attempting to expand.

PHS's method of expansion is simple but effective. As it enters a new part of the state, it forms a local physicians' corporation (the individual practice association or IPA) which in turn contracts with the physician-controlled HMO (PHS). The IPA corporation reimburses the local physicians on a fee-for-service basis, with the physicians agreeing, contractually, to share the responsibility for the total cost of medical-surgical care delivered by the IPA. This is done by withholding 20% of the physician's fee and putting it into a common risk pool to be redistributed among all the participating physicians if the IPA operates within its budget for the year. There are currently three IPA corporations contracting with PHS, with more planned as PHS expands into other parts of the state.

In three words, PHS is an extremely positive response by local community physicians to the increasing demand by Connecticut residents who greatly prefer this prepaid system to the other staff-model HMO which employs physicians, and also to the spotty coverage and unpredictable disallowances of traditional health insurance. PHS has grown into a $40 million-a-year, physician-controlled organization which, frankly, Blue Cross and Blue Shield is terribly concerned about because most of PHS's projected growth is going to come from enrollment which the Blues currently have. The Blues' response, as mentioned earlier, has been twofold. First, to establish staff-model HMOs (which employ physicians and operate out of a central facility) throughout the state using their significant financial resources and the management skills of the state's largest staff-model HMO, CHCP in New Haven. Their second response is to try to outflank PHS by setting up their own statewide IPA/HMO network (the Constitution Health Network or CHN). Whether physicians will choose to associate with this Blue Cross IPA/HMO in areas other than Hartford and Tolland Counties remains to be seen. But the choice for physicians is becoming clear: associate with a physician-controlled and -sponsored IPA/HMO (such as PHS), or associate with a Blue Cross and Blue Shield IPA/HMO (the Constitution Health Network). As discussed earlier, physicians do not realistically have a third choice which is to do nothing. For by doing nothing, the physician risks being locked out of any managed health system at a time when Connecticut residents are increasingly aligning themselves contractually with one prepaid health plan or another.

By selecting a managed health system such as Physicians Health Services, Connecticut physicians will, in this author's admittedly biased opinion, be maintaining their control over the health care delivery system, albeit a different one than the unstructured system they have known throughout their professional careers. They will be assuring that these new managed health systems can be a boon for the private fee-for-service practitioner. By selecting a health system managed by another party (such as Blue Cross and Blue Shield, a hospital, or a major insurance carrier), Connecticut physicians may, at best, simply be re-inventing Blue Shield, or at worst, strengthening a system which could function much more at cross-purposes with the interests of the local fee-for-service practitioner than Blue Shield ever has. This type of managed health system would almost certainly be a bane for the Connecticut physician community.

The moment of decision is at hand for many Connecticut physicians. For many other physicians it will soon be at hand. Hopefully this article has clarified the issues and physicians will make the right choice. Far better that physicians join a managed health system which they can control than remain outside of any such system or associate with one which may not be in their long-term best interest.

"ECONOMIC GRAND ROUNDS Implementation Guide" has been distributed to both the hospital administrator and medical staff chief of each of the nation's 7,000 acute care hospitals. The 96-page AMA publication was designed for use in cost-cutting efforts. The manual, which is the result of pilot testing at 110 hospitals around the country, was sent with letters from AMA Executive Vice President James H. Sammons, M.D., and Alex McMahon, president of the American Hospital Assn. Economic Grand Rounds is the first project of Cost Effectiveness Evaluation Network, which consists of hospitals that have agreed to test new ways for increasing the efficiency of clinical practice in the inpatient setting.

—AMA *Newsletter,* October 9, 1984.

RESIDENCY TRAINING PROGRAMS offered 21,331 first-year residency positions last July, according to a survey conducted by the AMA Office of Educational Directories. Currently there are enough positions for all U.S. graduates, although some individuals may not find a position in the specialty or location of their choice. Based on the number of postgraduate year one (PGY-1) positions reported for July 1, 1984, there were 1.3 positions for each new U.S. medical student entering this year. Contrary to rumors that the number of PGY-1 positions was decreasing and that positions were being withdrawn, the AMA special survey found the same ratio holds true for 1984 U.S. graduates—that is, 1.3 positions per graduate. In recent years, an average of 82% of new U.S. medical school graduates have been successful in obtaining a position through the National Residency Matching Program each year. About 17% of U.S. graduates obtain positions outside the match, usually by taking one of the 10% of available positions that were not offered in the match or one of the positions that was offered but not filled through the match. There are indications that the number of available PGY-1 positions is related to the quality of candidates seeking positions. Program directors have reported that they eliminated positions that they could not fill with the candidates of their choice. Some directors said they filled the positions with PGY-2 candidates. More slots were offered through the match this year than last. 86% in 1984 compared with 82% in 1983. Even so, the listing of positions has slipped from the 90-92% of previous years. "The Match nevertheless remains the best available mechanism for bringing candidates and programs together," said Office Director Anne E. Crowley, Ph.D.

—AMA *Newsletter,* October 9, 1984.

Hospital Bylaws vs. Medical Staff Bylaws

KHALIL A.I. CASSIMALLY, M.D.	:	
Petitioner,	:	IN THE CIRCUIT COURT OF THE
VS.	:	NINETEENTH JUDICIAL CIRCUIT IN AND FOR
LAWNWOOD MEDICAL CENTER, INC.	:	ST. LUCIE COUNTY
a Florida corporation	:	STATE OF FLORIDA
Respondent.	:	

THIS CAUSE coming on to be heard on the Petition of KHALIL A. I. CASSIMALLY, M.D., seeking a Writ of Mandamus* against the Respondent, LAWNWOOD MEDICAL CENTER, INC., a Florida corporation. The petition seeks to have the Court require the Lawnwood Medical Center conduct an election to elect the Medical Staff Officers, who traditionally have been elected in December of each year for a one year term. The Court heard the original petition on April 19, 1984 and continued it until April 27, 1984. The Court took testimony, heard the argument of counsel and has had the benefit of Memorandum of Law provided by both petitioner and respondent.

THE COURT determines that it has jurisdiction of the parties and further the Court has the authority to grant or deny the Petition for Writ of Mandamus filed herein.

THE COURT makes the following findings of fact:

1. The Court finds that Lawnwood Medical Center is a wholly owned subsidiary of the Hospital Corporation of America. Lawnwood provides general hospital services for the City of Fort Pierce and its environs and is the successor to the Fort Pierce Memorial Hospital, which was a charitable organization, whereas the Lawnwood Medical Center is a for profit corporation. However, that distinction now has been done away with, as set forth in the case of Carida v. Holy Cross Hospital, Inc., 427 So.2d 803, page 805-806:

   "[2] When West Coast Hospital Association v. Hoare was decided, chapter 395, Florida Statutes (1953), applied to both private and public hospitals; but twenty years elapsed before the Florida Legislature enacted section 395.065. By inclusion in that chapter, the statute did away with the public versus private hospital distinction in denying or restricting medical staff privileges. Further, it established the substantive and procedural requirements to be employed by all hospitals in this critical area of concern and restricted liability to instances of malice. The standards of the Joint Commission of Accreditation of Hospitals (JCAH) to which the statute referred and which apply to private hospitals were predicated on fairness of hearing and appellate review mechanisms. Two years after the enactment of the statute, the Department of Health and Rehabilitative Services (HRS) promulgated Rule 10D-28.58(2)(d), Florida Administrative Code, which imposed upon all hospitals the requirements of a hearing and thorough investigation of applications for appointment and reappointment to medical staffs."

2. The Board of Trustees of Lawnwood Medical Center is the governing body of the hospital. The board adopted bylaws to govern the hospital on August 24, 1978. These particular bylaws also called for the establishment of medical staff bylaws governing the conduct of the doctors on the medical staff, as well as the election of the medical staff officers. The board's bylaws now conform to Chapter 395 of the laws of Florida and Regulation 10D-28.56 of the Florida Administrative Code Annotated, which was adopted by the Department of Health and Rehabilitative Services, and states as follows:

   "10D-28.56 GOVERNING AUTHORITY. The Hospital organization shall have an effective governing authority responsible for the legal and moral conduct of the hospital as a functioning institution.

   (1) The governing authority in fulfilling its responsibility shall be organized under approved written bylaws, rules and regulations which shall:

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*Writ of mandamus: A writ is issued by a superior court commanding the performance of a specified official act or duty.

EDITOR'S NOTE: The reader must keep in mind that this case applies only to Florida, and also that this is a lower court decision.

(g) Provide for the approval of the bylaws, rules and regulations of the medical staff.

3. In accordance with the hospital's Board of Trustee's Bylaws the Medical Staff Bylaws were adopted by the Medical Staff on October 26, 1978, which is also now in accordance with Florida Statutes 395 and Rule 10D-28.58, Florida Administrative Code Annotated, adopted by the Department of Health and Rehabilitative Services, which states:
   "10D-28.58 MEDICAL STAFF. Each hospital shall have a medical staff organized under written bylaws approved by the governing authority and responsible to the governing authority of the hospital for the quality of all medical care provided to patients in the hospital and for the ethical and professional practices of its members."
4. The Court also finds, which is not binding on this Court, that the Joint Committee on Hospital Accreditation also requires the Medical Staff to have its own bylaws and to be able to elect its officers at its annual meeting.
5. The Medical Staff of Lawnwood Medical Center has conducted elections regularly at its annual December meeting until December, 1983 when the Board of Trustees amended the board's bylaws by adding to Article II, Section 3, Paragraph 1, the following language, which is underlined:
   "1.Responsibility for the medical, professional, and ethical activities of the hospital, including medical staff appointments and reappointments, the granting of medical staff privileges and the establishment of the organization and committees necessary for the proper and ethical conduct and the monitoring of all clinical activities, *including the appointment of all officers and members of the Medical Executive Committee when, in the best judgment of the Board of Trustees, such appointments are necessary for the continued and proper care of patients and, the discharging of its responsibilities referred to above."
6. Pursuant to the amendment adopted by the Board of Trustees, the Hospital Administrator appointed the Medical Staff Officers for the year of 1984 and this Petition for Mandamus ensued.
7. The modern view holds that the Medical Staff Bylaws, when approved by the Governing Board of the Hospital, become a contract between the hospital, operated by the Board of Trustees, and the physicians composing the Medical Staff. See the following cases: Berberian v. Lancaster Osteopathic Hospital Association, 395 PA 257, 149 A.2d 456 (1959); Joseph v. Passaic Hospital Association, 26 NJ 557, 141 A.2d 18; Miller v. Indiana Hospital, 277 PA Super 370, 419 A.2d 1191 (1980); The Anne Arundel General Hospital, Inc., et al. v. O'Brien, et al., 49 MD. App. 362, 432 A.2d 483 (1981); St. John's Hospital Medical Staff v. St. John Regional Medical Center, Inc., 90 S.D. 674, 245 N.W. 2d 472 (S.D. 1976); O'Leary, et al., v. Board of Director, Howard Young Medical Center, Inc., et al., 89 Wis.2d 156, 278 NW 2d 217 (1979).

   In the Passaic Hospital case cited above the Court held:
   "The medical staff bylaws were ratified by the Board of Governors, and thereby became a constituent part of the association's elemental law."

   Also, in The Anne Arundel Hospital case, the Court stated:
   "It is well settled that hospital bylaws have the force and effect of an enforceable contract."

   Also, in the St. John Hospital case cited above, the Court held also that the Medical Staff Bylaws were an enforceable contract when they were approved by the hospital Board of Directors, here at Lawnwood Hospital that would be the Board of Trustees.
8. This Court finds that the Appellate Courts of Florida have not addressed this proposition, as to whether, once the governing board of a hospital approves the medical staff bylaws, the medical staff bylaws then become a contract between the staff physicians and the hospital?
9. This Court finds that the common law in Florida is still alive and well; therefore, this Court declares that the common law of Florida is: That once the governing board of a hospital approves the Medical Staff Bylaws, these bylaws become a contract between the Medical Staff and the hospital and can only be amended as called for in the Medical Staff's Bylaws and not unilaterally by the Governing Board, which at Lawnwood Medical Center is the Board of Trustees.
10. This Court is adopting what it considers to be the modern view, as set out in the cases cited above.
11. The Court finds that the Board of Trustees nor its Administrator had the authority nor the right to appoint the Medical Staff Officers and those officers appointed by the Board of Trustees, while acting as such Medical Staff Officers under such appointment may be defacto Medical Staff Officers, but are not the de jure Medical Staff Officers of Lawnwood Medical Center.

It is therefore

ORDERED AND ADJUDGED that an Alternative Writ of Mandamus be issued to Lawnwood Medical Center, Inc., requiring it, its Officers and Board of Trustees to provide an immediate Medical Staff election in accordance with the Medical Staff Bylaws of that hospital.

DONE AND ORDERED in Fort Pierce, Florida, this 21st day of May, 1984.

/s/RUPERT JASEN SMITH
CIRCUIT JUDGE

Continuous Ambulatory Peritoneal Dialysis (CAPD)

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Since implementation of the Medicare End Stage Renal Disease (ESRD) Program in 1973, the number of patients receiving benefits under this program has increased dramatically. In 1980, approximately 55,000 patients received benefits at a cost to the nation of 1.2 billion dollars. This figure does not include expenditures from other sources such as private insurance and Medicaid. Since Medicare coverage has been extended to virtually any patient requiring dialysis care, more and more patients are being accepted for long-term dialysis who have severe complicating illnesses, and in whom the potential quality of life achievable on dialysis is limited. More than 5% of the total Medicare budget is now being spent on dialysis and transplant patients who represent less than 0.2% of the active Medicare patient population. Since 1973, the percentage of patients on home dialysis in the United States has declined steadily from 43% to approximately 11% of the total dialysis population. In view of the overriding economic, ethical and humanitarian concerns regarding this program, any new innovation in the management of end-stage renal disease is heralded with great interest. The technique of continuous ambulatory peritoneal dialysis (CAPD) represents an exciting new technique which may provide a very valuable treatment option for many patients requiring maintenance dialysis treatment. The potential economic ramifications are significant since the widespread usage of CAPD could rapidly increase the percentage of patients on home dialysis outside of an approved dialysis facility.

Most of the 55,000 patients with ESRD are treated in one of 850 approved dialysis facilities in the 32 network areas established by the Bureau of Quality Assurance of the Health Care Financing Administration. A small number, perhaps 3,000 patients per year, receive kidney transplants. At the present time, approximately 6,500 patients have been trained to provide their own dialysis treatments three or four times each week at home. The remainder, ± 45,000 patients are afforded staff assisted dialysis treatments in an approved facility. Even for home dialysis patients, frequent visits are made to the physician or dialysis center for monitoring medical status and blood chemistries. Although technical and medical advances have greatly improved the quality of life for most patients undergoing chronic dialysis, it remains less than optimal because the patient is tied to his dialysis machine in the center or at home. Because of the intermittent nature of treatments, steady state chemistries are never achieved and many patients do not feel well except for brief periods following dialysis. Finally, the cost remains significant at approximately $30,000 per year for in-center dialysis, and $18,000 per year for home dialysis by 1980 estimates. CAPD could have a significant impact in view of a lower estimated cost of $15,000 per year.

Peritoneal dialysis has been available as a temporary treatment in the management of acute renal failure for the past 30 years since the availability of commercially prepared dialysis solutions and disposable plastic administration equipment. Early on, the procedure was not considered for the long-term treatment of patients with ESRD because of the significant risk of peritonitis and other complications. Increasing interest in utilization of the peritoneal cavity for long-term dialysis accompanied the introduction of a chronic, silastic, indwelling peritoneal dialysis catheter (Tenckoff catheter) and the development of automated delivery systems. These two technologic developments provided a semi-closed dialysis system which resulted in the reduction of peritonitis to an acceptable level of 0.5% to 1% of treatments administered.

In 1976, Popovich, Moncrief and colleagues described the technique of continuous ambulatory peritoneal dialysis for the treatment of chronic renal failure. Modification of this technique by Oreopoulos and colleagues to utilize dialysate in two liter plastic bags has resulted in rapid acceptance of CAPD as an alternative treatment for many patients with ESRD requiring dialysis therapy. The bags are connected to the permanent peritoneal catheter by a short plastic tube

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Action of the House of Delegates; Report B of the Council on Scientific Affairs *adopted.*

with appropriate connectors at each end. After inflow, the bag, still attached to the connection tube, is carried rolled up in a cloth waist purse under the clothing. At the end of the diffusion, the dialysate is drained into the same bag which is then discarded and a fresh bag is attached to the same connection tube. The patient exchanges two liters of dialysate four or five times a day, seven days a week. Progressive experience with this new system has been associated with a reduction in the incidence of peritonitis from one episode every eight to ten patient weeks of dialysis to as little as one episode every 12.6 months. The recent experience of Oreopoulos and colleagues suggests that the incidence of peritonitis can be reduced to even lower levels by giving precise attention to sterile technique. Most patients who develop peritonitis can be treated on an outpatient basis rather than requiring an expensive hospitalization for antibiotic therapy. There is reason to think that further technological developments should reduce even further the risk of accidental contamination and catheter exit site infections.

Advantages of CAPD

Experience with this procedure has demonstrated the ability to maintain blood chemical measurements in a more physiologic, steady state than can be accomplished with intermittent hemodialysis or peritoneal dialysis. Stable body weight and total body potassium, as well as stable serum proteins, suggest that protein losses are easily replaced by an adequate dietary intake and significant protein depletion is rarely noted. Diabetes mellitus is more easily controlled by CAPD, often by adding insulin to the dialysate bags, thus obviating the need for daily insulin administration by subcutaneous injection. Hematocrit readings and dry body weight may increase in many patients, and blood pressure control is more easily achieved and maintained on CAPD than with traditional intermittent dialysis.

Perhaps the greatest advantage of CAPD is an intangible one, that is, improvement in overall quality of life for the patient. The patient is free from a machine and manages his dialysis independently at work or at home. On changing from machine dialysis at home or incenter, the patient discovers that he can travel by carrying spare dialysis bags in a suitcase, or even return to a job by making one or more bag exchanges at the work site. Because of the continuous nature of the dialysis, patients have an increased sense of well-being without the ups and downs often experienced with intermittent hemodialysis or peritoneal dialysis. Since rapid fluid shifts are avoided, consequent problems in managing blood pressure are not as frequent. Preliminary cost estimates suggest that the operational costs of CAPD are significantly lower than the costs experienced with intermittent dialysis techniques. Similarly, since CAPD is performed outside the hospital environment, the technique facilitates dialysis for a larger percentage of patients with ESRD.

Limitations of CAPD

The risk of peritonitis still discourages many physicians from using CAPD for their ESRD patients. The invading organism is usually a skin saprophyte (e.g., staphylococcus), however, the recovery of an infecting organism is not accomplished in 4% to 10% of the cases. During the infection, protein losses in the dialysate are greatly increased. However, prompt response to intraperitoneal antibiotic therapy is usually seen, and the rapid clearing of the infection can be expected when recognized early and treated promptly. With recurrent peritonitis, peritoneal permeability and peritoneal clearance of waste products (solutes) may be impaired.

Another complication of CAPD is the development of obesity and marked hypertriglyceridemia in some patients. This is apparently a consequence of a high concentration of glucose (4.5%), sometimes instilled intraperitoneally to enhance fluid removal. A high carbohydrate intake is known to stimulate or “induce” an elevation of serum triglycerides in susceptible patients. The long-term effects of such a hyperlipidemia are not established, but the possibility of accelerated atherogenesis is a justifiable concern.

Other drawbacks include the tediu of frequent exchanges of dialysate using sterile technique, problems of cuff erosion and sinus tract formation that can be attributed to the catheter, and other problems related to ESRD that may be anticipated with any method of dialysis. Many reports attest to the fact that some patients prefer machine dialysis at home or kidney transplantation over CAPD. However, when patients are carefully selected, many will elect and prefer CAPD.

Patient selection is of obvious importance, although criteria have not been fully established. It is clear, however, that CAPD is not appropriate for all patients with ESRD. Patients must be highly motivated and must have the intelligence to learn the techniques and apply them precisely. It is thought that they must be healthy enough—that is, free of other debilitating illnesses—to enable them to function physically and psychologically without assistance. On the other hand, in a careful retrospective study of psychosocial parameters in 260 ESRD patients on home dialysis or CAPD in the Province of Ontario, no significant differences were found between several parameters: blood chemistry levels, work status, sexual functioning, Rotter’s scale on internality vs. externality, or in the basic personality inventory score. Between patients on CAPD and those on home intermittent dialysis, the one inconvertible difference was in the number of hospital admissions required for peritonitis.

Conclusions

Currently, CAPD is offered in more than 400 approved facilities to more than 4,000 patients in the United States. There are over 10,000 patients under treatment with this technique throughout the world.

CAPD has been declared a reimburseable alternative to chronic intermittent dialysis therapy under the Medicare ESRD Program as of September 1979. It represents a useful alternative to intermittent hemodialysis or peritoneal dialysis. It can be presented to ESRD patients as an alternative form of therapy that need not be mutually exclusive of other forms of management.

It may be too soon to determine the ultimate role of CAPD in the management of end-stage renal disease. However, even at this early date it can be observed that:

1. CAPD is a viable alternative to other means of managing ESRD;
2. CAPD promises to be from 30% to 50% less expensive than home intermittent dialysis, so that it has the potential for a true savings to the Medicare reimbursement system;
3. There is reason to believe that many ESRD patients will find CAPD to be a more satisfactory way of life than intermittent home dialysis or center dialysis;
4. The complication of peritonitis, which may require expensive hospitalization, remains a problem to be overcome by improved patient selection, improvements in technology and better training of patients in the use of the technique.

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Summary Of Malpractice Claims Against Physicians By Location

1983

During 1983, 5,199 malpractice claims against physicians insured by The St. Paul were reported to the company. The data at right identifies where the claims occurred and the average cost of those claims. Hospital operating rooms were the most frequent place of occurrence for claims reported in 1983, while claims resulting from incidents which took place in obstetrics units had the highest average cost.

LOCATION	NUMBER OF CLAIMS	PERCENT OF CLAIMS	AVERAGE COST
PHYSICIAN'S OFFICE	936	18.0%	$25,260
CLINIC	412	7.9	21,053
HOSPITAL–EMERGENCY ROOM	642	12.3	24,836
HOSPITAL–OPERATING ROOM	1,680	32.3	35,324
HOSPITAL–OBSTETRICS	424	8.2	64,364
HOSPITAL–PATIENT CARE AREA	615	11.8	37,565
HOSPITAL–OUTPATIENT SURGERY	50	1.0	14,815
HOSPITAL–OTHER AREAS	274	5.3	23,685
SURGI-CENTER	43	0.8	29,334
OTHER LOCATIONS	123	2.4	
TOTAL	5,199	100%	

—*Malpractice Digest*, March 1984

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Avoiding Pitfalls in Retirement Plan Investing

GEOFFREY T. ANDERS, J.D., CPA, CPBC, LEIF C. BECK, LL.B., CPBC, DOROTHY R. SWEENEY AND J. THOMAS MARTIN, J.D.

Despite the now reduced retirement plan contribution limits imposed by the Tax Equity and Fiscal Responsibility Act of 1982, physician assets in Keogh and Corporate retirement plans will still represent the cornerstone of most doctors' accumulated wealth. The importance of those funds in the physicians' overall financial planning demands that continuing attention be paid to investment matters. Even where investment responsibility is delegated to a bank or other investment manager, the doctor or group must continue to monitor results.

Failure to supervise performance of invested dollars has resulted in almost as many "horror" stories as have stock market and life insurance investments. A five doctor surgical group we recently visited has happily salted away substantial monies in their corporate retirement plans for the last ten years. Inattention to investment results over those years has resulted in returns of about 1% per year! Even the traditional savings account would have been dramatically better. Similar examples crop up repeatedly; most of which could have been avoided with relatively little effort.

Plan Investment Objectives

Given the pre-eminent position of retirement plan dollars as a storehouse of wealth, the first objective of plan investing must be safety or "perservation of capital." There are a number of reasons.

While the funds are accumulated for retirement, an intervening disability or the doctor's death may require the funds well in advance of a planned retirement age. Losses from risky investments or investments whose prices fluctuate substantially do little to insure that the monies will be there when needed.

The primary advantage of Keogh/corporate plans is that earnings are tax sheltered until withdrawn. Thus the fund's income feeds on itself over the years, growing geometrically since unreduced by taxes. Losses interrupt the scheduled compounding both by reducing the fund as well as by setting back the accumulation schedule. A loss of $10,000 at age 35 represents $100,000 at age 65 if income at an average 8% rate would have been earned.

Investment risk should only be undertaken to achieve better than average returns. Physicians, by and large, do not need to assume extra risk since they will be able to reach personal and family financial objectives within the usual economics of medical practice. Thus there is little pressure to achieve maximum results.

Retirement funds invested on a safe but sure approach will certainly hit the mark eventually. And if extra funds are accumulated through risky investments *outside* the plan, so much the better. The point is that the basic retirement game plan is not left to the chances of the financial markets.

Diversification of investments goes hand in hand with safety. Any one type of investment or mutual fund or bank may suffer reverses in a given economy or market. Investing in several or many situations spreads the risk so that a severe economic dislocation should not result in a loss of all the funds. On a less catastrophic basis, poorer results from one investment may, in a diversified portfolio, be offset by a high return elsewhere, resulting in an overall reasonable return.

Only partial diversity is obtained by investing in one money market or other mutual fund. Those vehicles do offer protection from too great a loss from the failure of one invested-in corporation. Little or no protection exists from the mutual fund's own failure. Thus retirement plan dollars should be spread among several institutions if these investment choices are used.

The "prudent man" rule which governs retirement plan investing comes into play here. Retirement dollars invested through one medium or institution simply may not measure up to the required standards since modern portfolio theory demands more. Thus an undiversified investment plan which suffers losses may subject the doctor or doctors to employee lawsuits as well as the loss of their own funds.

The authors are the principal consultants of The Health Care Group, Bala Cynwyd, PA. The Health Care Group, formerly Management Consulting for Professionals, deals exclusively with problems confronting medical practices.

Some thought should be given to plan investment liquidity in view of the overall circumstances. A portion of the funds should certainly be readily convertible to cash without risk of penalty either by loss of interest or by market losses. Liquidity insures the availability of cash to meet, perhaps, unexpected pay-out demands, to permit investment in any unexpected opportunity and simply to be available in the event a corporate plan participant might wish to borrow personally from the retirement plan.

In addition to general reasons for keeping some amount of assets convertible to cash quickly, the doctor's personal financial planning may add another reason. As a very general rule of thumb, where less than $250,000 is invested, a distribution from the plan is best made in a "lump sum" (paid out within one calendar year) in order to take advantage of special income tax advantages. Thus it may be well to limit investment to very liquid items or to investments which would be desirable for a doctor's beneficiaries to help insure the most tax advantage at least until significant amounts have accumulated within the plan or plans.

Those priorities lead to our basic investment philosophy for physicians' retirement plan dollars: *Limit retirement plan investments to interest producing, high quality investments with relatively short maturity dates.*

The bugaboo of such an approach and the hue and cry of more aggressive investment approaches is inflation. While obviously not good, the threat of inflation to a safe but sure strategy has been blown very much out of proportion.

While return on investment dollars may be below apparent inflation rates, physicians' incomes and thus the ability to contribute to retirement funds have by and large offset reductions in purchasing power. Thus if annual contributions increase by the perceived inflation rate overall, an investment return slightly below inflation does not do significant harm. Where the alternative is accepting greater and greater levels of risk to "beat inflation" and possibly not only not matching inflation but losing the original investment, the 90% of a loaf approach should be quite acceptable.

This analysis assumes that fixed interest investments never exceed inflation. In fact, bond and certificate of deposit returns have compared quite well with the GNP deflator—a much more accurate measure of inflation than the Consumer Price Index. Furthermore, periods of real return exist. A case in point is 1982 where inflation at most totalled 6% but where money market returns averaged at least 10%. These periods of real return help to offset purchasing power losses.

Investment Alternatives

Within our basic priorities, a review of the more popular or at least most publicized plan investments may help the reader see the pitfalls involved and where many choices fall short as retirement plan investments.

Stocks. Investments in stocks are perhaps the most visible alternative since the up and down gyrations of the Dow Jones Averages receive so much news media attention. We believe that stocks are a particularly unattractive retirement plan investment possibility.

First, physicians generally have little time or interest in becoming expert in the stock market so investment decisions are typically delegated, either formally or de facto, with the doctors rubber stamping their investment counselors' recommendations. The use of investment counselors, stock mutual funds and bank trust departments has its own set of difficulties discussed below.

Secondly, stock investments are not the tax-wise choice for a tax sheltered plan. Stocks are generally bought with a view to long-term capital gains. If those gains are achieved with personal monies, the tax rate at maximum is 20%. In a retirement plan, however, the gains lose their tax-preferred nature—ultimately being paid out as 50% taxable dollars. On the other hand, stock investment losses, which inevitably occur, are tax deductible if made personally. A loss in an already tax sheltered plan is useless. With the exception of utilities, REITs and an occasional other stock, yields on equity investments simply have not kept pace in recent years with interest paying investments. The low yields do not make good use of the earnings compounding opportunity of retirement plans. Since that opportunity is a major advantage, stock investments fall short of the optimal range of choices.

The failure to produce a healthy, current rate of return can be made up by writing call options against a portfolio of stocks. The plan receives a premium (in the range of 10% to 15% of the stock's value) in exchange for selling the right to buy the stock at a set price during a stated time period. While some good returns have been achieved this way, the approach seems schizophrenic. If the stock's price is thought to be going up, the sale of an option is counter-productive since it limits the upside opportunity (the stock will be called away if the price rises too much). If the stock's price is expected to decline, it would simply be better to sell the stock.

In terms of safety, the stock market ranks very poorly. The risk is two-fold. There is the risk that a particular investment may go sour even where large, well-known companies are involved. The cases of Penn Central, Lockheed, Franklin National Bank, Chrysler and Johns Manville are just a few of the examples over recent years. Even without that type of risk there is the more pervading "market" risk. The doctor simply cannot count on the stock market being "up" when he or she wants to cash in the chips and retire. Many personal plans have gone astray simply because retirement funds have been tied to the vagaries of market fluctuations.

Despite our strong feelings against stock investments for Keogh and corporate plans, some physicians will choose that route. If so, two comments are in order.

Stock investments perform best over *long* periods of time. The doctor within ten years of retirement should not begin a stock investment program.

Secondly, a systematic stock investment approach may show the best overall results. For example, plan contributions might be made monthly and initially be parked in a money market account. Each month one-half of the regular monthly contribution would then be moved to a stock mutual fund. When the cost of the mutual fund shares increases, the percentage invested should decline leaving the balance of that month's contribution in the money market to earn interest until a more suitable stock buying point occurs. If the fund's shares decline in value, an increased percentage of the monthly contributions should be invested in stocks. While this formula approach requires some calculation and close attention, results over the long run should be quite satisfactory since investments are geared to reducing the overall average cost of stock fund purchases.

Corporate Bonds. High grade corporate bonds are a reasonably acceptable choice within our investment parameters. Market risk can be virtually eliminated by purchasing bonds with only moderate length maturities, perhaps not more than five or seven years in the future, and holding the bonds for that period. That way fluctuation in interest rates and market conditions will not affect the anticipated return.

This approach is only possible with the purchase of bonds directly and not by buying shares in bond funds. Buying individual issues, however, means that some risk is accepted—the failure of the company prior to the bonds' redemption. This risk can be minimized by both staying with very high grade bonds and by short maturity dates. A corporation's finances can be fairly well predicted three to five years in the future, but after that estimates of financial strength tend to be little better than pure guesses.

One good approach using bonds is to invest roughly equal amounts in bonds coming due over each of the next five years. When the present year's maturities roll around, the dollars are then reinvested in bonds to come due five years in the future. This method insures a fairly good degree of liquidity since in any year 20% of the fund will turn to cash. Furthermore, the serial reinvestment assures that an average rate of return is achieved over the period so that the portfolio is not left behind in the "keeping up with inflation" game.

Life Insurance. To the life insurance industry, Keogh plans and professional corporations have presented an outstanding sales opportunity. In our view, however, tax free retirement plans are definitely not the vehicles for the sensible purchase of life insurance.

Most physicians are now aware that traditional whole life insurance is simply not competitive when compared to other steady, interest producing investments. Premiums paid simply reduce the dollars available to otherwise compound at reasonable rates of interest. Even worse, life insurance to some extent destroys the tax sheltering mechanism of the retirement fund. The value of the present life insurance coverage (often called the P.S. 58 cost) is taxed currently to the doctor and must be reported on his personal income tax return.

The newest life insurance products, called "universal life" and similar names, promise an improvement over traditional whole life insurance. It appears that these products will offer a better, though probably not competitive, return. And they will still suffer from the defect of part of the premiums becoming taxable income. So while some aspects of this type of vehicle are not yet clear, universal life does not appear to be a suitable retirement plan investment.

At present, there are further reasons for staying away from such purchases. Insurance industry executives describe the universal life policies currently being offered as primitive and expect great improvements over the next several years.

Other Investment Choices. U.S. Treasury notes, U.S. Agency notes, bank certificates of deposit, money market mutual funds and the like are good choices within our overall retirement plan philosophy. Each provides a good degree of safety and regular return. Careful selection of maturity dates is still needed, however, to obtain reasonable rates of return over several years and to meet liquidity needs. An eye might also be kept on the approximately four year span between interest rate peaks affecting these investments to lock in better yields with a larger proportion of the available dollars.

Government National Mortgage Association (GNMA) pass-through certificates may also be quite good choices, but only for larger practices. GNMA's provide an excellent return and repayment of principal and interest is guaranteed by the U.S. government. The one fly in the ointment is the length of time until the certificates are fully paid off. This problem is lessened since a portion of principal in addition to interest is returned each month so that fewer dollars are invested overall as time passes. GNMA certificates can also be sold but that subjects the investment to market fluctuations and thus possible loss. Still the *average* life of a GNMA certificate is twelve years and may go on to thirty years—either time span being far too long for investment by a solo or small group's retirement plans.

Real estate investments are simply not appropriate for retirement plans in our view, although they may be appropriate as a personal investment choice. Tax losses which real estate usually throws off are of no value to the plans. A fair degree of market risk exists since real estate prices do fluctuate significantly. Worst of all, real estate is perhaps the most illiquid form of investment offering no assurance that a property could be sold when cash is needed.

Investment Advisors

The search for a good, consistent investment advisor has been compared to the search for the Holy Grail. We tend to agree. Advisors have at best inconsistent results since whoever seems to have a "hot hand" in one year inevitably does poorly in the next. The failure to achieve consistent results is quite understandable. Most advisors follow a particular format which may work quite well in one market or under a particular set of economic conditions. When those conditions change, however, the format no longer works and bad results ensue.

This difficulty cannot be overcome by employing a large institution—a bank or insurance company usually—to handle investments. Overall, bank trust departments did best between 1963 and 1972 when compared to insurance companies and investment counselors. From 1971 to 1981 investment counselors performed best, followed by insurance companies and then the banks. So even with professionally managed, diversified funds there is a lack of an on-going "best" choice.

It is also important to note that investment returns by insurance company, bank and investment counselor managed funds have been only marginal. During the 1972-1981 period, investment counselors, the best of the bunch, achieved a median, annual return of less than 5%!

Even the choice of an investment advisor, or manager, does not relieve the doctor or group of responsibility. The developing size of retirement assets requires that doctors give good attention to these funds, no matter how much he or she may wish to stay out of investment decisions. Simply the choice of an advisor is a decision of great importance. That decision is an on-going one since the question of changing to another advisor is always present. Thus time and judgment must be spent in selecting an advisor, regularly reviewing results and deciding to continue as in the past.

Since these investment decisions cannot be avoided, we believe the doctor may be just as well off directly managing his own retirement plan funds. Adopting our underlying investment philosophy virtually permits intelligent choices by even financially naive investors.

Conclusion

While we are not investment counselors, we have seen so many physician client situations that we have formed fairly strong opinions on retirement plan investing. While not particularly exciting, our choices result from identifying primary goals and concentrating on achieving those goals as surely as possible.

"ENOUGH IS ENOUGH!" must be organized medicine's firm response to the Reagan Administration's efforts to cut health care spending even further than it has. This was the message that AMA President Joseph F. Boyle, M.D., delivered to the House of Delegates during the Dec. 2-5 Interim Meeting in Honolulu. "We must not stand impotently by" as Budget Director David Stockman proposes further cost-cutting measures, Dr. Boyle said. The nation's physicians have succeeded in slowing the growth rate of health care expenditures "despite an expanding and aging population needing and receiving steadily increasing medical services and in the face of a steadily growing, miracle-making fund of technology," he said. In a speech interrupted four times by applause, Dr. Boyle pledged continued efforts to curb increasing health costs "because we believe in economy and efficiency." He emphasized, however, that "we must send a clear signal to the country that we can generate more enthusiasm and cooperation from our colleagues, and indeed do a better job, without new doses of the kinds of remedies the Administration and the Congress have been dispensing."

—AMA *Newsletter,* January 8, 1985.

Month in Washington

Budget Cuts Planned For Health

Among a host of health-related budget proposals Reagan Administration health and budget advisers are pondering for fiscal 1986 is a continuation of a Medicare freeze on physician fees.

All budget discussions at this point are in preliminary stages and White House officials say no mechanics of a freeze have been worked out. It is not even clear, for instance, that the freeze would cover all physicians. Nor have any final decisions been made on which of a laundry list of possible health program cuts will be included in the plan the President will send to Congress in late January or early February. But the President has told his staff that deep cuts will be made in all discretionary programs and a freeze on all government programs except Social Security.

In addition to the physician fee freeze, a variety of other previously-offered administration health budget initiatives are expected to be on the platter for next year as well. These include a number of recommendations from the conservative Heritage Foundation, which has close ties to the administration, as well as some that Congress has rejected in the past.

The Heritage Foundation, which has distributed a thousand-page report to the Reagan cabinet, wants to "modify" Medicare's diagnosis related groups price controls through the addition of provisions intended to enhance market competition.

All were offered in the President's first term but never garnered adequate support in Congress. They include a proposal to improve Medicare coverage for catastrophic illness while increasing cost-sharing for shorter hospital stays; Medicare vouchers; and a tax on employer-provided health benefits above a certain limit.

The tax cap, which has substantial opposition in Congress, would reduce current subsidies estimated to cost the federal government $17.6 billion in lost revenues. Medical expense write-offs reduce federal income by another $3.2 billion and charitable contributions to health organizations another $1.4 billion. All three could be eliminated in a simplified tax plan the Treasury Department is developing.

The cost-sharing portion of the catastrophic illness benefit also faced major difficulties in Congress and the provision budget officers are considering this year reportedly would set up a new premium to cover the cost of the catastrophic coverage. Another possibility is to require private employers to include catastrophic protection in workers' health insurance.

The voucher proposal is also said to be on the budgeteers' list along with increases in the part B premiums and deductibles and major changes in the funding of graduate medical education. The latter could include replacing the current Medicare contribution to the direct cost of medical education with a block grant and discontinuing the indirect cost allowance for all but the largest teaching hospitals.

Medicaid, which was hard hit in earlier rounds of budget cutting, could also be hit again, although Congress may balk at any further cuts in this program. Possibilities include: a 3% reduction in federal Medicaid payments to states where "health costs are excessive when compared to nationally established growth rate targets"; changes in the matching payment formula; or an across-the-board reduction in federal payments.

* * * *

Appropriations, Hospice Home Care Bills Signed

As one of his first post-election duties, President Reagan signed on November 9 a $79.6 billion appropriation bill for the Department of Health and Human Services and a measure raising Medicare rates for hospice home care.

The appropriations measure which funds HHS programs through October 1, 1985, includes money for the National Institutes of Health and Human professions education programs that will continue despite the President's earlier veto of bills reauthorizing these programs. The NIH is to receive $5.15 billion; nurse and health professions training programs, $234.5 million.

The hospice bill would restore the home care payment to $53.17 a day. HHS had initially proposed this rate but reduced it to $46.25. A veto threat was withdrawn in the face of the considerable public and bipartisan Congressional support for the hospice movement.

Prepared by the Washington, D.C.
Office of the American Medical Association

* * * *

PRO Contracts Complete, Feds Bid Out Super PRO

With just six days to spare before a Congressional deadline for implementation of the fledging peer review organizations (PROs), Health Care Financing Administration officials on November 9 signed the last three PRO contracts.

The officials now are awaiting bids for another contract—dubbed the Super PRO—to evaluate and monitor the PROs.

Also still to come are four sets of PRO regulations that have not yet been issued in final form.

As had been predicted, Idaho will be the only state in which the review authority has been delegated to a Medicare intermediary. There, the Idaho Blue Cross plan will be paid its cost for the PRO reviews of hospitalized Medicare patients' care. A $1.3 million spending limit has been placed on the contract, however.

HCFA negotiators had initiated talks with the Hawaiian intermediary. Blue Shield of Hawaii, after a plan to have the California PRO assume review in Hawaii and the Pacific Islands fell through. Negotiations with the Arizona PRO proved more successful, however, and that contractor was also awarded the $1.28 million Hawaiian contract and the $227,000 contract for Guam and Samoa.

The Arizona PRO (the Phoenix-based Arizona Health Services Advisory Group) is one of only two for-profit groups that won PRO contracts. The other is the Pennsylvania Peer Review Organization in Camp Hill.

Meanwhile, federal officials are gearing up to keep a watchful eye on the PROs. The new review organizations have considerably more authority than their predecessor Professional Standards Review Organizations, and HCFA staff is concerned that the PROs apply their power with sensitivity. There have been a few early reports of impolitic actions and letters among some PROs that have probably unnecessarily angered hospitals and physicians in their area.

The federal PRO management team will also be keeping tabs on progress PROs make toward meeting the stiff new admission-reduction and quality-enhancing goals the winning organizations set for themselves. Staff from HHS' Inspector General's Office also will be looking at the PROs as part of their overall task of monitoring Medicare's prospective pricing system. Super PRO will play a critical role in the monitoring process.

Bids on the Super PRO contract were due by November 30 and several organizations, including the American Medical Association, were bidding.

The winner will be scrutinizing the PROs medical review decisions to assure that they are "consistent" and "appropriate" and that they are made by "appropriate staff or representatives."

In addition to selection of the Super PRO, the new peer review groups are still awaiting publication of four sets of final PRO regulations, including a controversial proposal governing confidentiality of data collected by the PROs. Proposed confidentiality regulations that made public data on identifiable individual hospitals were criticized by hospitals and physicians as too loose. Representatives of business, labor and the elderly want to eliminate the proposal rules' protection of individually identifiable physician data.

Other regulations still to come will govern the conduct of review, sanctions and appeals.

A recent regulatory agenda published in the Federal Register anticipates publication of a final regulation by the end of December. Another set of regulations governing conditions under which Medicare will pay for certain services later found to have been unnecessary is still being drafted.

* * * *

Wennberg Method Proposed To Reduce Variations

A greatly expanded federal investment to reduce variations in medical practice from community to community might save Medicare up to $16 billion a year and reduce surgical death rates in the process, says a physician epidemiologist who has studied such variations for 10 years.

Dartmouth professor John Wennberg, M.D., wants Medicare and Medicaid to follow industry's example of setting aside a specific percentage of expenditures for research. He has suggested that about 0.5% of the Medicare trust fund outlays be devoted to this purpose. At estimated 1984 spending levels this would amount to nearly $300 billion if all spending were included.

The research Dr. Wennberg has in mind would monitor and compare surgical and hospital admission rates community by community. It would also compare the outcomes of alternative treatments for some conditions where physicians don't agree on the best approach.

In addition, the Dartmouth medical school professor thinks federal funding to medical schools should be contingent on the schools' teaching statistical and epidemiological techniques that would help physicians choose between treatments.

His premise is that with documentation of the variations and better outcome studies, physicians will voluntarily reduce the variations. Since he has found low utilization rates among some teaching hospitals, he believes uses rates—and therefore costs—can be lowered without harming quality. In many cases, he suggests, care would simply be shifted from hospitals to physicians' offices so physicians' incomes would not be greatly affected by the change.

One indication of the growing attention Wennberg's methodology is attracting came as a November 19 hearing of the Senate Appropriations Subcommittee on Health and Human Services. Hearing Chairman Senator William Proxmire (D-WI) said he sees the Wennberg approach as a possible way to avoid cuts in Medicare benefits. A variety of witnesses, including the American Medicare Peer Review Association, the Washington Business Group on Health, and the American Medical Association supported Wennberg's approach but had different interpretations of it.

AMA representative James E. Davis, M.D., speaker of the Association's House of Delegates, emphasized that medical societies have participated in some of Dr. Wennberg's studies and saw as one of its virtues the emphasis on "voluntary practice modification rather than intrusive governmental intervention."

The Durham, North Carolina surgeon added, that while the AMA does believe that "wide variations" in care "should be examined closely," they may be "an indicator" of the "failure to provide care" as well as a signal that inappropriate care has been provided.

AMPRA Vice President Thomas Dehn, M.D., whose organization represents physician-directed peer review groups, including some of the new PROs, said Dr. Wennberg's work points to the need to extend PRO reviews into outpatient settings.

Washington Business Group on Health executive Willis Goldbeck saw the Dartmouth researchers' findings as evidence that business needs more data on hospital and physicians, and that Congress should require a relicensure system for physicians. Although Goldbeck also implied that some practice variations stem from usual, customary and reasonable payments, Wennberg himself has said that the variations are a "worldwide phenomenon not explained by incentives associated with fee for service medicine."

Health Care Financing Administration staff, who are clearly uneasy with the prospect of a Medicare set-aside for research, maintained that the recent advent of a Medicare prospective payment system and peer review organizations (PROs) are already encouraging physicians to rethink their practice patterns. Nevertheless, HCFA official Henry Desmarais, M.D., announced, the agency is "considering" Dr. Wennberg's method as "one of several approached within the new PRO program to further refine the identification of variations in physician patterns." Some PRO officials have reported that HCFA is negotiating a demonstration of a Wennberg computer program by the Iowa PRO.

* * * *

Court Orders Nursing Home Inspection Guidelines

A federal court in Denver has ordered the Department of Health and Human Services to rewrite guidelines for inspecting the nation's 18,000 nursing homes to emphasize actual care of patients rather than the structure of the home.

The ruling by the US Court of Appeals comes as a prestigious national committee is holding a series of public hearings on nursing home standards and regulations and as both states and the federal government are beginning to look for better ways of monitoring the care nursing home patients receive. Federal officials said they haven't yet assessed the potential impact of the Colorado suit and haven't decided whether or not to appeal the decision.

The suit was based on the argument that by concentrating on structural issues, federal Medicare and Medicaid standards concentrate only on the homes' potential to provide care rather than the quality of care actually provided.

Although a lower court ruled that enforcement of nursing home standards is a state responsibility, the appeals court found that HHS was not meeting a statutory obligation to assure that nursing home patients receive quality care and instructed the lower court to "compel" the department to meet its obligations in this area.

The issue raised in the Colorado decision involves a long argument over the types of standards nursing homes participating in Medicare and Medicaid should be required to meet and how they should be monitored.

It was put on hold when congress directed HHS to hold off on any changes in the enforcement procedures for a short time and then won a "gentleman's agreement" with the department that changes in the conditions of participation and inspection process would be delayed pending the recommendations of a national commission.

The commission, which was formed through the National Institutes of Medicine, is now conducting public hearings and expects to issue its final recommendations in July, 1985. Congress in the interim also increased the funds for inspection which rose to $73.6 million in 1983 and were at $72.5 million in 1984.

Meanwhile several states have initiated new inspection and survey methods aimed at looking less at facilities' physician structure and more at the end result in terms of guality of care and the degree to which the patients' other needs are met as well. The Health Care Financing Administration is involved in five of the state efforts and is also experimenting with a new national survey instrument. Both the nursing home industry and patients rights groups support a move to an outcome oriented approach.

* * * *

President Challenges New Council On Health Care Technology

In a tersely worded message to Congress, President Reagan this month warned that he would not request funding for the new Council on Health Care Technology, a quasi-private clearinghouse for technology assessment.

Although Reagan signed S-771, which authorized the Council, he noted "strong objection" to the constitutionality of the group.

The Council would be composed of members chosen by the federal Department of Health and Human Services and the private National Academy of Sciences, including federal officials, members of the general public, and representatives of the fields of medicine, law, ethics, economics, and management.

Reagan contended that the council would mix governmental and non-governmental, executive and legislative elements "in a manner which in inconsistent both with the Constitution and with sound government practices," he said. Because the Council would perform government duties, it is unconstitutional for its members to be selected by a nongovernmental agency, he noted.

The President asked Congress to go back to the drawing board, revamping the structure and function of the Council. Until such remedial legislation, he will refuse to ask for funding for the Council in his January budget.

* * * *

Another Blow To Depo-Provera

Citing inadequate research, a Food and Drug Administration advisory panel has recommended that the injectible contraceptive Depo-Provera not be approved for sale in the US.

The panel of three university scientists said that data linking the long-term use of the drug to cancer in animals should not be ignored. Depo-Provera was found to produce breast cancer in beagles over a seven-year period and endometrial cancer in monkeys over a 10-year period.

The panel's recommendation, endorsed by other FDA scientists, now goes to FDA Commissioner Frank E. Young, M.D., for a final decision. If Dr. Young agrees with the panel's conclusion, as expected, manufacturer Upjohn Co. may go to court to have the FDA action overturned.

Depo-Provera, approved in 80 foreign countries, has been used by 11 million women around the world. If approved in the US, an estimated four million women may have shifted over from other contraceptives. Additionally, the drug could have been used in overseas population programs sponsored by the US Agency for International Development.

The drug is effective for over three months and requires less patient motivation than the pill or barrier contraceptives. It is injected into the muscle of the upper arm or buttock and released slowly into the bloodstream from the injection site. It can be administered by any person who normally gives injections.

It prevents ovulation by suppressing hormone production by the hypothalamus and pituitary. Secondary effects, such as changing the cervical mucus, the uterine lining, and the Fallopian tubes, also reduce fertility.

Its use is endorsed by a wide variety of health and population groups, such as the World Health Organization, the American College of Obstetrics and Gynecology, the International Planned Parenthood Federation, and the Population Crisis Committee.

Opponents include FDA staff scientists, individual scientists from the National Cancer Institute, the Centers for Disease Control, and consumer advocacy groups such as the National Women's Health Network and the Health Research Group.

* * * *

FDA Considers Banning Sale of Raw Milk

The Food and Drug Administration (FDA) is considering a regulation that would ban the sale of raw milk, in hopes of reducing cases of bacteria-linked poisoning.

Advocates of raw milk contend that pasteurization reduces levels of thiamin, vitamins B-12 and C, calcium, protein, and fat. Raw milk has been claimed to contain beneficial enzymes, hormones, and anti-stiffness agents for treatment of arthritis.

Many recent outbreaks of salmonellosis, however, prompted government officials to take a closer look at raw milk. Milk is an ideal growth medium for Salmonella, they discovered, causing severe diarrhea, abdominal cramps, and sometimes death. California health authorities have calculated that the risk of Salmonella dublin infection is 84 times higher in persons who consume raw milk than in persons who consume pasteurized milk.

Moreover, pasteurization causes no major loss of nutrients, FDA researchers found. There is no evidence that raw milk enhances resistance to disease, improves fertility, or reduces stiffness, they say. The so-called beneficial enzymes inactivated by pasteurization are also inactivated by gastric acidity and hormones are unaffected by the pasteurization process, they note.

FDA's proposal was applauded by the AMA, which believes that all milk sold for human consumption should be pasteurized. "There is convincing scientific evidence that raw milk poses a significant public health risk," said AMA Executive Vice President James H. Sammons, M.D. "Pasteurization kills the bacteria that transmit disease to humans."

* * * *

New NIH Guidelines

A new report from the Institutes of Medicine (IOM) warns against further expansion of the National Institutes of Health (NIH), but urges NIH to become more aggressive in its response to public health needs.

If NIH does a better job at responding to health emergencies, perhaps Congress will ease up on efforts to create new institutes, the IOM report suggests.

The report was prepared by a 15-member IOM committee over the past 18 months, in response to a request by the Department of Health and Human Services to study the organizational structure of NIH. The committee received written comments from 145 organizations and individuals and interviewed 185 people, including members of NIH, HHS, Congress, and the scientific and medical communities.

Part of the report received a warm reception: virtually everyone agrees that the NIH Director deserves more freedom to respond to sudden research needs. Proposals which give the NIH Director access to a discretionary fund and the authority to transfer some funds across NIH institute lines were endorsed by both the research and congressional community.

There is dispute, however, over the report's criteria for establishing new institutes. Since 1970, there have been 23 separate proposals for new institutes. Researchers say that the once-unified mission of NIH has become fractured and splintered as disease groups lobby for special attention.

The most recent push for NIH reorganization, which would have authorized a new arthritis institute and nursing institute, was vetoed by President Reagan in November.

* * * *

Cancer Rates Improving

Survival rates for cancer victims are showing a slow but gradual improvement, climbing from 48% for patients diagnosed from 1973-75 to 49% for patients diagnosed from 1976-81, according to new National Cancer Institute (NCI) statistics.

Most noteworthy are gains in survival of cancers of the lung (12-13%), colon (49-52%), and prostate (64-70%).

Overall there were gains against rare diseases such as testicular cancer, Hodgkin's disease, melanoma, and the vast array of childhood cancers and leukemias, but little progress in the more common cancers of the breast and endometrium.

Cancers with the highest five-year survival rates are: thyroid cancer, 93%; testis cancer, 86%; endometrium cancer, 85%; melanoma, 80%; female breast cancer, 74%; bladder cancer, 73%; Hodgkin's disease, 73%; and uterine and larynx cancers, 67%. Cancers with the lowest survival rates are: pancreas cancer, 2%; esophagus cancer, 5%; and stomach cancer, 16%.

In some cases, NCI says increased survival rates are due to improved drug therapy; in others the turnaround is due to better recognition of early lesions by patients.

* * * *

FDA Offers Help To Halt Fraudulent Medical Ads

The Food and Drug Administation (FDA) and the Council of Better Business Bureaus have asked the nation's radio and TV stations to review medical claims carefully before accepting them in advertisements.

To help, FDA and the Council are mailing 10,000 sales managers information about how to recognize medical product frauds. The mailing suggests careful checking of proposed ads that depend on sensational or foreign testimonials, state or imply that established medicine is covering up a "breakthrough," or have vaguely worded "money back" guarantees.

If TV and radio sales managers have questions about a claim or company, the Council and FDA are ready to help. A similar mailing was sent to newspapers and magazines in May.

Among bogus products as frauds are "miracle" weight reducers, herbs and health foods sold with disease claims, body wraps, sex aids, arthritis and cancer "cures," simplistic tests for diet deficiencies and allergies, anti-aging products, sobriety aids and multipurpose elixirs and treatments.

* * * *

Medical PACs Come Of Age In 1984 Elections

Behind the scenes in recent elections, political action committees (PACs) quietly have come of age. Strong and savvy, they have established themselves as major fixtures on Washington's political scene.

Nowhere is this more evident than in health PACs. AMA's PAC (AMPAC), once the only major contributor to health-oriented candidates, has been joined by more than 100 smaller, more specialized contributors.

AMPAC boosted spending 60% during this election cycle, from $2.4 million in 1981 to an estimated $3.5 million in 1984. Abbott Labs increased contributions 28%; Eli Lilly increased contributions 22%. Hospital chains, medical device companies, medical specialty societies, and non-physician professionals all report healthy spending levels.

Candidates who once spurned a PAC's advances this year turned to them for help. PAC spokesman say they received unprecented numbers of invitations campaign cocktail parties and dinner fundraisers.

Even some staunch opponents of PACs have adopted a "if you can't beat 'em, join 'em" philosophy and contributed to politicians who best represent their interests.

Some of the changes noted in fundraising this past election cycle:

- Earlier spending—larger "war chests" of contributions are carried from election to election, saved for future use. Supporters of this accelerated spending say that "early money" makes candidates less vulnerable to the debts incurred by their re-election campaign.

- Increased pressure—as the cost of running for office climbs, candidates must look for new ways to make ends meet. "Reverse lobbying," in which candidates solicit PACs, is now the trend. Some large PACs ask challengers to fill out questionaires, complete "position paper" and discuss issues. Even small PACs say they receive daily invitations to fundraising parties.
- More risk taking—as PACs become more adept at identifying qualified challengers, they have shifted away from the play-it-safe approach of backing only incumbents and are making a greater effort to locate those challengers who support their interests.
- Restricted spending—increasingly, PACs look for ways to exert the greatest influence on the handful of Congressional candidates they most want in office. FEC's limits on PAC spending can be sidestepped by "independent expenditures;" as long as a PAC has no contact with a candidate or his campaign, there is no ceiling on the amount it spends. Spending was very high in this area in 1984.
- Greater specialization—not long ago, AMPAC was the only medical PAC in town. Now, there are PACs for pathologists, psychiatrists, emergency physicians, and oral and maxillofacial surgeons. Black physicians are represented by the National Medical Association PAC; public health physicians, Public Health PAC; and anti-war physicians, Medical Associates for Peace PAC. Non-physician health PAC are also active; in the 1983-84 election cycle, dentists spent roughly $679-680; chiropractors, $213,814; nurses, $185,662; optomotrists, $177,974; podiatrists, $134,954 and so on.
- Changed expectations—gone are the days when a voting record could pinpoint candidates who were for or against medicine. The battle lines are often blurred. PACs now look for legislators who share philosophical leanings, or who are particularly knowledgeable about a certain area of health.

* * * *

Post-Election Wrapup

President Reagan's landslide victory is unlikely to make a major difference in physician's professional lives as both the newly-elected Congress and the returning administration continue to chip away at costs in an industry that is seen as a key part of any effort to reduce the federal deficit.

Presidential advisers are terming the vote a mandate for continuation of Reagan policies which appears to signal a continuation of efforts to reduce spending for social programs—including Medicare and Medicaid.

Others contested the contention that the President has won a mandate and pointed to the President's failure to convince the voters to give him a "working majority" in the Congress.

The GOP regained only 14 of the 26 seats that it needed to restore a coalition of Republicans and conservative Democrats that combined to push major Reagan initiatives through Congress before the mid-term election reduced Republican numbers in the House. The Democrats will have a 71-seat majority. In the Senate, Republicans retained control but Democrats picked up two seats, reducing the Republican edge in that body to 53 to 47 in the new 99th Congress.

Thus, while the President can expect a slightly more cooperative House of Representatives, his support in the Senate has been slightly diminished. Although the Democratic to GOP balance on House committees may be minimally altered, the shift is not expected to have a major impact on control of the committee process by Democrats.

Perhaps the major change resulting from the elections is the retirement of Senate Majority Leader Howard Baker and the ascension of Kansas Republican Robert Dole to the leadership post. Dole has a reputation for speaking back to the White House and under his guidance, the Senate could prove more independent than under Baker.

Dole will be relinquishing his key chairmanship of the Finance Committee to Senator Robert Packwood, a moderate Republican, who has sometimes been regarded as a maverick. He has generally supported and been supported by organized medicine.

As head of the Senate Commerce Committee, however, Packwood did oppose the American Medical Association's effort to eliminate Federal Trade Commission controls over the professions. He is an opponent of taxes on employer-paid health insurance premiums and of restrictions on a woman's right to an abortion.

Most other important transformations in Congressional panels with jurisdiction over health legislation also occur as a result of retirements. On the House Ways and Means Committee, two Democrats—James Shannon of Massachusetts and Kent Hance of Texas—are retiring. So are Republicans Barber Conable of New York and Jim Martin of North Carolina. In line to step up to the widely-respected Conable's ranking minority spot is John Duncan (R-TN) who has been a friend to health providers but may not have the influence Conable did.

On the House Energy and Commerce Committee, three seats are changing. New York Democrat Richard Ottinger and Illinois Republican Tom Corcoran retired. Tennessee Democrat Albert Gore Jr. will move to the Senate where he won the seat of retiring Senate Majority Leader Howard Baker (R-TN). Gore, who frequently used his post on the Oversight and Investigations subcommittee to conduct hearings into controversial medical issues, played a major role in the passage of an organ transplant bill that was initially opposed by the American Medical Association but was modified in later Congressional deliberations.

The President's Page

A New Year

The recent election results may give organized medicine, physicians in general and our patients an opportunity to have more influence on the legislative process than we have had for many years. Many deeply entrenched incumbents, whose opinions are contrary to those of us in health care, have been defeated and with their demise has gone their allegiance to other groups and individuals whose concern for our patients has been measured in dollars rather than the quality of care given our patients. I am certain there will be bills introduced into the general assembly which will have an impact on all of us. In addition changes are necessary in current legislation to make it more palatable to physicians and their patients.

The state and county medical societies are now geared up, more than ever before, to lead us into the legislative battles. Never, in the past fifteen years have we been as organized. Moreover, our Connecticut Medical Political Action Committee (COMPAC) has never been in better shape, with more members and more funds to distribute than ever before. In the last elections, COMPAC gave modest support to 102 candidates in the 193 races for federal and state legislative offices. A remarkable 88% of COMPAC-backed candidates won election! Unfortunately, a mere 7% of CSMS members, through their support of COMPAC, were responsible for our success. COMPAC ran out of money long before it ran out of good candidates to support to the maximum legal level. However, you can help set this right by responding to the COMPAC appeal enclosed in your dues mailing this month. (Personal checks only).

And besides this, there still is a great deal more that can and must be done. It behooves each and every one of us to contact our county or state organizations and offer our services to the legislative committees if we feel our services may be useful in effecting legislation beneficial to our patients as well as to us. I also personally make a plea that each Society member read his mail and call or write his legislator when a request to do so is made. Unified, we can have some control over our destinies as well as that of our patients. Please follow your legislator and contact him regarding your views.

Joseph S. Sadowski, M.D.
President

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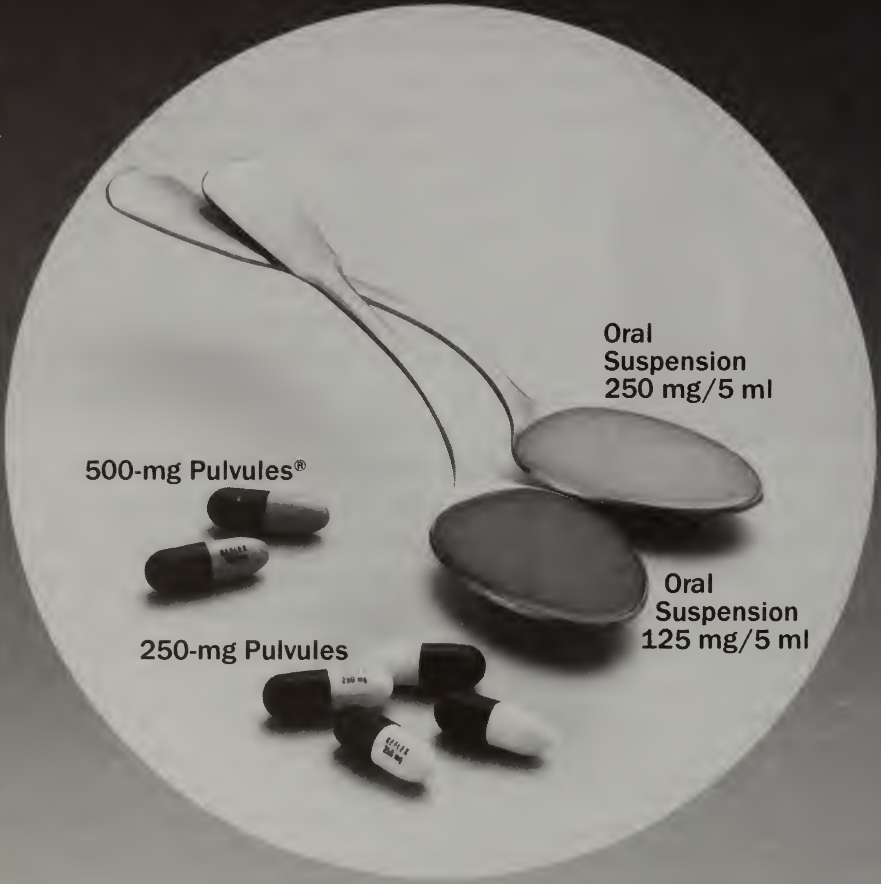

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Reflections from the Dean's Office

Virchow's Legacy

ROBERT U. MASSEY, M.D.

Recently a fellow dean who shares with me an interest in the history of medicine asked if we had ever discussed Rudolf Virchow in our seminars. We had, I was happy to tell him, six or seven years ago, invited a fellow from the Johns Hopkins Institute of the History of Medicine to lecture on Virchow's concept of disease as revealed in *Die Cellularpathologie* of 1858. We doubted whether most medical students would have heard his name except in connection with the supraclavicular lymph node sometimes felt in metastatic tumors, rarely in gastric carcinoma, and which, when I was a medical student, everyone called Virchow's node.

In his obituary which was read before the German Pathological Society on 22 September 1902 Virchow was called "the leader of medicine in the nineteenth century, the reformer of pathology, and a master both of biology and anthropology." It is difficult for us after 83 years to appreciate the extent of the changes in medicine attributable to his work.

The medical reforms which he had in mind as a 25 year old pathologist in 1846 when he read his paper "Concerning Points of View in Scientific Medicine" were all one with the political and social reforms sweeping over Europe from France in the years just before 1848. His support for "full and unlimited democracy" got him into trouble with his political masters, and he was dismissed from the University of Berlin. His obituary writer referred to yet another claim to fame: "Already as a young pathologist Virchow emphasized the great significance of medicine for human society and called it a social science."

Virchow had grown up in the decades when philosophical systems and mystical romanticism dominated German medicine. The doctrines of *Naturphilosophie* rather than observation and experimentation provided the explanations for natural events, and debates ran on endlessly about whether disease was in the humors or in the solid parts. For Virchow, disease was no interloper seizing possession of the organs or humors but rather "an expression of individual life under unfavorable conditions." Both pathological anatomy and the manifestations of disease were the observable changes arising from *Pathologische Physiologie.*

So also in society, "epidemics must be indicative of major disturbances of mass life." From this came his famous aphorism: "Medicine is a social science, and politics nothing but medicine on a grand scale."

He insisted that cellular pathology was a principle, not a system. So skeptical was he of anything which sounded like dogma that he could never accept the notion that microorganisms could be the sole cause of disease. He did not attend the meeting of the Berlin Physiological Society on the night of 24 March 1882 when Koch presented his conclusive evidence for the bacterial etiology of tuberculosis. Perhaps he adhered too closely to his own concepts, but he has been vindicated in his belief that bacterial agents are but one factor in the causation of disease.

The botanist, Matthias Jacob Schleiden had shown that the fundamental unit of plant life was the cell; Theodore Schwann demonstrated the same for animals, thus establishing "one universal principle" for all life. They both believed, however, that cells arose from, were crystalized out of, non-cellular material, the cytoblastema.

It remained for Virchow to prove that all tissues, even bone and cartilage, came from cells, and that each cell derived from a preexisting cell. *Omnis cellula e cellula,* at least for the higher forms. Not until Pasteur was the controversy over spontaneous generation finally settled.

He returned to Berlin in 1856 and remained until his death in 1902. He continued active in politics first as a member of the Prussian lower house, later in the Reichstag as leader of the opposition; he served for years on the Berlin City Council where he helped to achieve reforms in school health and hospital construction, and was instrumental in cleaning up the water supply and providing for an adequate sewage system. He even took time to help Schliemann in his excavation of Homer's Troy.

For him, medicine was the most encompassing of all the sciences, the unified study of man undertaken to perfect human society—an impossible goal but surely one loftier than the "bottom line" implied in the concept of a health care industry.

In a recent article, Leon Eisenberg wrote, "Medicine may employ technical means, but it functions normatively for human ends. Assessment of its benefits and its costs must be on social, not technical, grounds."[1] That is the legacy of the great reformer.

REFERENCES

1. Eisenberg L: Rudolf Ludwig Karl Virchow, Where are you now that we need you? Am Jour of Med 77:524-532, September, 1984.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington, CT.

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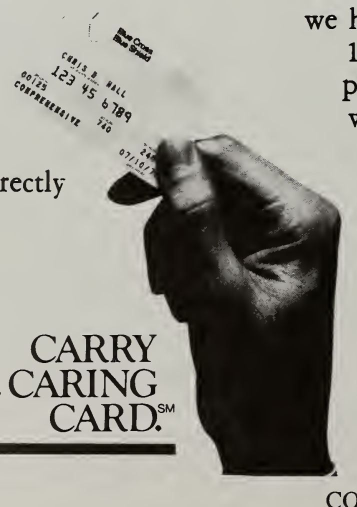

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Deciding for the Incompetent Patient: The Development of Public Policy

JOSEPH M. HEALEY, J.D.

There have been many interesting developments in legal aspects of death and dying during the past few months. These developments underscore the progress being made toward clarifying ambiguities and establishing clearer policies and procedures for decision-making involving dying patients. In Georgia, the state Supreme Court held that the family or a legal guardian may make the decision to terminate life-support systems, without prior judicial approval or consultation with an ethics committee, in cases involving patients who are terminally ill or in a chronic vegetative state with no reasonable possibility of regaining cognitive functioning.[1] In New York, the highest state court, the Court of Appeals, accepted the concept of brain death.[2] In Minnesota, the state Supreme Court held that a conservator had the right to exercise substituted judgment on behalf of an incompetent, comatose conservatee, though it left unclear the circumstances in which prior court review would be necessary.[3] In Connecticut, an important Superior Court decision[4] and a state statute[5] recognizing brain death have provided a firm foundation for the development of Connecticut public policy in these areas.

Sandra Foody was a forty-two year old woman who following respiratory arrest was taken to the emergency room of Manchester Hospital. She was successfully resuscitated, intubated and placed on a respirator. She was semicomatose, unable to breath without the respirator. Her parent-conservator brought suit seeking to discontinue the life support systems without subjecting those involved to civil or criminal liability. Ms. Foody had suffered from multiple sclerosis for twenty-four years. During that period the disease had become progressively severe. By the time of her respiratory arrest, she could not sit up on her own, nor hold her head up, nor speak so that others could understand. Medical evidence presented at trial suggested that in all probability she had no congnitive function. Her semicomatose state was not believed to be attributable to multiple sclerosis but to an aspiration while eating which produced acute respiratory arrest, causing insufficient oxygen to the brain. Since there was no sign of improvement after two months of treatment, her condition was considered to be permanent and irreversible.

In a well-reasoned and thorough opinion, Judge Hennessey reviewed the nature of the patient's right to refuse treatment, the state interests which might outweigh such a right, and the mechanisms to be used to permit exercise of such a right for an incompetent adult. The court held that:

> "Where the incapable patient's condition (1) is permanent and irreversible and there is no reasonable medical probability that the patient ever will return to a cognitive state, (2) the patient's attending physician together with at least two other consulting physicians unanimously concur as to the patient's condition, and (3) there are concerned family members who in good faith wish to exercise through substitute decision-making the patient's right to discontinue artificial life-support systems, it is our conclusion that the family lawfully may act as the patient's substitute decision maker and may decide to discontinue the use of the respirator . . . "[6]

As a decision of the Superior Court, this case has limited precedential value. I also have my concerns about the range of discretion given to surrogates who have not been appointed by the Court. Nonetheless, the case represents an important first step in clarifying Connecticut public policy in this area.

Also of interest to Connecticut physicians is the recent statute accepting the concept of brain death. The statue reads:

> Section 1. For purposes of making a determination concerning the continuation or removal of any life support system in a general hospital licensed under section 19a-491 of the general statutes, an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. Determination of death shall be made in accordance with accepted medical standards.
>
> Section 2. For the purpose of this act, "life support system" means any mechanical or electronic device utilized by any medical facility in order to replace, assist or supplement the function of any human vital organ or combination of organs.[7]

During the past few years, there have been at least two Connecticut hospitals who were reluctant to use the concept of brain death in declaring a patient dead. This statute should put an end to such reluctance.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

(The references deleted because of space limitations will be published next month).

The Resident's Page

Second Annual Connecticut Residents Cancer Symposium

It is once again time to begin planning and preparing for the Connecticut Residents Annual Cancer Symposium. This year the symposium will again be held in conjunction with the Annual Meeting of the Connecticut State Medical Society at the Parkview Hilton Hotel in downtown Hartford on May 9, 1985.

As residents we all face patients suffering with cancer every day. This symposium is an opportunity to present some of that extensive experience and share it with the other residents of the State of Connecticut. Eight papers will be presented and the best papers will receive a cash award as well as recognition and a plaque. In addition, you may submit winning papers for publication in *Connecticut Medicine*.

Each presentation will be allotted ten minutes, with five additional for discussion and questions from the floor. In this way, give and take will be encouraged and we will get maximum chance to really share what our colleagues have learned.

We would like to have papers presented on a broad range of topics of interest to the clinician fighting cancer. Particularly interesting would be those reports describing interdisciplinary approaches to cancer therapy. Comparative studies, clinical trials, and outcome studies with analysis are only some examples of the type of paper that would be welcomed. Individual case reports, reviews of the literature, and basic research not readily applicable to the clinical practice of medicine are not suitable for this forum.

I would encourage all residents reading this to begin considering projects suitable for this presentation. Once underway, such a project often gains momentum and proves to be an enjoyable experience, but the greatest obstacle is getting started. There is no better way to learn about a topic than by presenting it to others, and even a ten-minute talk represents a very significant amount of learned material.

In addition, I have always found that preparing a research project or paper gives me a greater understanding of the literature in general and adds new insights and appreciation to the monthly journal articles. The time and efforts spent in developing and sharing a project are amply rewarded.

This is a particularly good forum for resident participation because it is designed by and for residents. This is our opportunity to present our own work and hear that of our peers. We get together to share and appreciate our colleagues' studies, and this is a good spot to bring together all discrepancies. Residents from across the state seldom have the opportunity to interact much, but this sort of interchange ought to be encouraged and sustained by this type of conference. The fight against cancer is one area shared by almost all residents, so this is common ground.

To enter please submit a double-spaced, single page abstract to:

Dr. Robert E. Sax, M.D.
782 Clinton Avenue
Bridgeport, CT 06604

Deadline for abstracts is February 28th, 1984. Please put authors' names and affiliation on a separate title page to allow blind judging. Final manuscripts selected for presentation will be done April 26th, 1985. Start planning now to make this Second Annual Residents Cancer Symposium even more successful.

Lee R. Morisy, M.D., *President*
CSMS Resident Physician Section

Connecticut Medicine

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160 St. Ronan Street, New Haven, CT 06511

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Editorial

Who Will Control Health Care?

The first Health Maintenance Organization to be established in Connecticut was Community Health Care Plan in New Haven over ten years ago. It is a staff model providing services now to over 40,000 members from facilities on Long Wharf in New Haven and in Wallingford. Connecticut Health Plan, another staff model, is operating in Bridgeport and recently these two have merged under the umbrella of a new corporation called Pre-Paid Health Plans of Connecticut. Connecticut Health Plan has about 10,000 members. Another staff model, Yale Health Plan, provides services to Yale University students and faculty and it has about 24,000 members, a figure which has remained relatively constant for the last five years. The newest closed panel model, Kaiser Foundation Health Plan, in the Hartford area, is a group model in East Hartford begun six years ago and operated by Kaiser for over two years. It presently has about 23,000 members and recently opened a second facility in Farmington, Connecticut. Four other HMO's in the state are in operation. They are Individual Practice Association (IPA) types or so-called open panel HMO's. Physicians have provided leadership in the establishment of these organizations and almost 2,000 physicians are participating in the delivery of care to subscribers of these plans. The first IPA's in Connecticut were Physician Health Services in Trumbull and Health Care in New Haven. These plans have been operating for over six years and are both interested in expanding their service areas throughout the state. ConnectiCare, which is the first hospital initiated IPA in Connecticut, began about three years ago through cooperative efforts of the administration and staff of Hartford Hospital. It presently has about 10,000 memters. The newest IPA is Constitution Health Network in the Hartford/Tolland County area. It represents a joint effort on the part of county medical associations and Blue Cross/Blue Shield. It became operational in January, 1984, has had the most rapid initial growth of any HMO in the state and is the 15th fastest growing plan in the country. In nine months it had 10,000 filiation with Blue Cross/Blue Shield, whose experience and resources have been beneficially utilized. Altogether, these eight HMO's are serving 170,000 people, a 40% increase in one year. There is every reason to expect that this number will increase rapidly in the next few years. Physicians are participating for at least two reasons. The first is that many doctors share the concerns of business, labor, and consumers for the high cost of health care, and they believe that HMO's provide the opportunity for conscientious control of these costs in a manner which will not impact unfavorably on the quality of health care. The second reason is that they perceive, with considerable justification, that an increasingly large pool of patients will be drawn away from the private practice of medicine unless physicians are willing to participate in this new type of health care delivery system. There is clearly an acceleration in the growth curves of HMO's in the past year throughout the country as well as in this state and it is likely to persist for some time. The business community has been increasingly supportive as they have sought mechanisms to impact favorably on their health care costs. Physicians have been increasingly supportive as they recognize cost as a factor in their decisions and seek ways to continue providing medical care while maintaining high quality services. To some degree who will control health care in the future depends on the extent to which IPA's, controlled by physicians, are successful in competing with closed panel plans.

Lawrence B. Ahrens, M.D.

Speaker, House of Delegates;
Medical Director and Vice President,
Medical Affairs, Constitution Health Network

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

LOGIC TO DISLODGE IT

To the Editor: The "Report of the Council on Scientific Affairs," adopted by the AMA House of Delegates (1983 Annual Meeting) discusses the relative effectiveness of the Heimlich Maneuver vs. Back Blows "in management of the acutely obstructed airway" (*Connecticut Medicine* Vol.48, No.9). Unfortunately, the "Recommendations" say little more than *try everything*, with no suggestion as to the order of preference.

Lacking in consideration of this vital scientific problem is any discussion of the mechanism whereby each method operates. How else can one intelligently approach the problem? Statistics are notoriously unreliable—and particularly here.

The goal, obviously, is to dislodge the material from the airway, bring it "up" and "forward" and "out." Simply dislodging it and having it sucked back by empty lungs defeats the purpose. Gravity can be helpful here by getting the patient's torso (and head and neck) tipped slightly forward. The heavier patient can lean forward over a chair-back if conscious. A child can even be totally inverted for thumping on the back, or held in a standing "prone" position for the "abdominal thrust."

The purpose of the abdominal thrust is to force air out of the lungs and thus dislodge the obstruction. What do back blows do? The average person who is struck on the back with force reacts with sudden inspiration, very undesirable at this point! The direction of the force of the blow is not "up," only "forward and out." Timing of the blow is essential. If the patient is conscious and can be calmed sufficiently, he should take in *very slowly* some air, enough to effect a reasonable cough. The back blow should be administered to the mid-thoracic vertebra at the exact moment the cough is released—or even a split second before, so that it almost triggers the cough. Thus, the foreign material will hopefully be shaken loose by the back blow and expelled by the air from the cough.

Incidently, I have used this form of back blow, placing one hand flat along the patient's mid-thoracic spine, having the patient take a deep breath and then striking my hand sharply with the other fist at the moment the patient (on instruction) coughs. This technique was used to clear the bronchial tree in post-operative adults of all ages for 35 years without *any* untoward results. So here for the conscious patient is a safe and reasonable method. Undoubtedly, back blows administered indiscriminately have some chance of being effective—but *much* less so.

The abdominal thrust does not require cooperation of the patient, since external force compresses the lungs and tends to force the air out through the larynx, hopefully carrying the foreign material with it. This maneuver can be performed with the patient in almost any position. However, the reports of fractured liver, esophageal laceration, emesis and aspiration, et al., indicate that this method is not entirely safe, despite its effectiveness.

To dislodge it, wouldn't logic then dictate that the back blow—properly timed—should be used first in the conscious patient? If after several attempts the airway has not been re-established, the abdominal thrust should then be used. Each method should be allowed and should take less than a minute. Expedition is important, but so is consideration and respect for the human body in such times of crisis.

E. Tremain Bradley, M.D.

Sanibel, Florida

MEDICAL COSTS AND QUALITY OF HEALTH CARE

To the Editor: Currently there are many plans and regulations to cut medical costs and yet maintain quality of health care. As a physician I am told what I can charge, what tests I can, must, or should not order, how long my patients can stay in the hospital and where they must go after discharge. No one has yet proved that this is proper and good health care. There is no question, however, that it will cut costs. If good health is a god-given right of our citizens, an opinion I fully believe, then good health of my patients must result if I adhere to the ever-increasing number of documents and rules mandated by the government, health care insurance and corporate health care plans and the like.

I would like to propose that the entire emphasis of cost containment be taken away from doctors, hospitals and labs—the deliverers of health care. Rather, the patient, the recipient of health care should and can be the prime factor to reduce health costs if he were obligated to follow guidelines and regulations instead of the deliverers of health care.

For example: An overweight patient with diabetes and hypertension would be given guidelines to lose ½ to 1 lb. a week, a very realistic goal. If he did not, he would not be reimbursed for his medical care. Think how much healthier he would be at ideal body weight and what cost reductions there would be in decreased hospitalizations for stroke, blindness, renal failure and the like.

Patients who continue to smoke should have to pay for their own vascular bypasses, lobectomies, inhalers and antibiotics. Patients who would know ahead of time that they would be obligated for these health care costs would, of course, stop smoking and hence reduce health costs. A more radical approach might be to deny them the actual surgery and medications because they continue to smoke. This would, of course, result in great reduction in health care costs but, of course, would not be good health care.

Other examples include the executive who does not reduce his stress and develops gastric or peptic ulcer disease, or the person who is involved in a car accident not wearing a seat belt, or the motorcyclist who is injured while not wearing a helmet. Should these patients not be liable for the cost of their own health care because of their own failure to follow guidelines which were issued to provide good health.

I feel strongly that until patients follow the advice of their physicians and start taking better care of their health, cost of health care will continue to spiral, not as the result of physician fees or hospital costs, or the expense of the technology now associated with delivering better health care but because of the poorer health of our population. If there are fallacies with my proposal—they are the same as those of the existing legislation and guidelines!

Barr H. Forman, M.D.

New Haven, CT

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

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SUMMARY OF PROCEEDINGS
HOUSE OF DELEGATES—SEMI-ANNUAL MEETING
Sheraton Bridgeport Hotel Bridgeport—November 15, 1984

Reports and Resolutions

The House of Delegates received reports from the President, the Council, the AMA Delegation, Connecticut Medical Political Committee (COMPAC), and the Executive Director. Resolutions were also received from the Council and individual members.

Principal Actions Taken

(a) **Report of the President,** Joseph S. Sadowski, M.D., Hartford: The House VOTED to accept the report of the President, which highlighted the formation of the CSMS sponsored Connecticut Medical Insurance Company (CMIC). Dr. Sadowski mentioned that he believed many more CSMS members, in addition to the original 930 participants, would join CMIC in the next few years.

(b) **Report of the Council,** Guy W. Van Syckle, M.D., Danbury: The House VOTED to accept the report of the Chairman of the Council, which reviewed the activities of the Council since the last meeting of the House of Delegates. Special emphasis was placed on the Society's Professional Liability Program, which culminated in the creation of the Connecticut Medical Insurance Company (CMIC). Also included were reports on Connecticut Peer Review Organization (CPRO), tort reform, a program on Public Affairs, the 1985 Budget, and the following items of old business, which were referred to the Council by the House of Delegates at its annual meeting on May 9, 1984.

1. The present methods for physician licensure in Connecticut; the credentialing process utilized by hospital in Connecticut; the present method of communication among the states, the status of individuals practicing medicine, with or without license, in or outside a hospital. (The House VOTED to circularize the report on this subject to the Chairman of the Credential Committee of each hospital with the recommendation that Hospitals follow the guidelines proposed.) patients; prospective pricing systems; fee schedules for physicians; and All-Payers legislation.

The complete text of these reports appear in the report of the Council which is published elsewhere in this issue of *Connecticut Medicine.*

(c) **Report of the AMA Delegation:** The House VOTED to accept the report of AMA Delegation, which was prepared by Guy W. Van Syckle, M.D. The comprehensive report contained all of the principal actions taken at the 1984 Annual Meeting of the AMA House of Delegates, some of which were on DRG'S, Hospital-Medical Staff Issues, Professional Liability, Health Care Costs and membership. Dr. Van Syckle also read a letter from Robert McAfee, M.D. of Maine, a successful candidate for the AMA Board of Trustees, thanking CSMS for their financial support ($5000) during his campaign.

(d) **Connecticut Medical Political Action Committee (COMPAC),** Patrick R. Concannon, M.D., Middletown, Chairman of COMPAC: The House VOTED to accept, as information, the report of the Chairman of COMPAC which mentioned that while the organization had more members than ever before, there is a need for greater participation in COMPAC by CSMS members.

(e) **Report of the Executive Director,** Mr. Timothy B. Norbeck, New Haven: The House VOTED to accept the report of the Executive Director which discussed the constitutional initiative sponsored by the Florida Medical Association, activities of the American Association of Retired Persons (AARP), the health care propositions which appeared on the Arizona ballot, and the impact the recent election might have on medicine.

(f) **Budget for 1985:** The House VOTED to approve the budget for 1985, as prepared and recommended by the Council with the recommendation that the dues remain at $175.

The House VOTED to adopt the following resolutions.

Resolution on Arbitration of Medical Liability Claims

RESOLVED: That the Ad Hoc Committee on Tort Reform Legislation examine all information on the subject to determine the need for and feasibility of using existing arbitration statutes in Connecticut and report back to the next meeting of the House of Delegates.

Resolution on Bioethics Committees in Hospitals

RESOLVED: That the CSMS adopt the policy that each hospital medical staff form a Bioethics Committee with locally determined guidelines regarding composition, definition of roles, responsibility and authority; and be it further

RESOLVED: That the CSMS adopt the policy that such a committee be available for consultation in those medical illnesses presenting clinical problems complicated by bioethical issues and that a committee be voluntary, educational and advisory in nature so as not to interfere with the primary responsibility of the physician to his/her patient; and be it further

RESOLVED: That this action be communicated to Chiefs of Staffs and Chief Executive Officers of hospitals.

Resolution on Medicare Assignment

RESOLVED: That in keeping with Medicine's time honored ethical principle that the physician's fee "be commensurate with the services rendered and the patient's ability to pay," the Society's House of Delegates urge CSMS members to continue to accept Medicare assignment or similar fee for any elderly patient who is unable to afford a physician's fee.

Resolution on Prescription Drugs for Senior Citizens

RESOLVED: That the Connecticut State Medical Society supports the concept of financial assistance by the proper state agency for those senior citizens deemed eligible for such assistance necessary to secure prescribed medications and medical supplies on an ambulatory basis; the mechanisms for such assistance to be developed in an equitable manner by the agency involved.

Resolution on a Continuing AMA Role in Interactive Educational Technology Development

RESOLVED: That the Connecticut State Medical Society request the AMA House of Delegates to ask the Board of Trustees to study the financial, scientific and public relations implications of continued AMA presence in interactive educational technology research; and be it further

RESOLVED: That the AMA Board of Trustees be asked to report its conclusions to the AMA House of Delegates at its next meeting.

Resolution on Support of Increasing the Public Awareness of the Importance of Using Automobile Seat Belts

RESOLVED: That the Connecticut State Medical Society reaffirm its support for increased public education on the advantages of automobile seat belt usage; and be it further

RESOLVED: That the Connecticut State Medical Society encourage its physician members to take a leadership role in advocating the use of automobile seat belts as an important preventive health measure; and be it further

RESOLVED: That the Connecticut State Medical Society support the work of the Connecticut Seat Belt Coalition, a statewide organization devoted to increasing public awareness on this subject, and be it further

RESOLVED: That the Connecticut State Medical Society support development of legislation concerning mandatory seat belts.

Other Business Considered by the House

Report on Public Affairs: In response to a Council action, the Committee on Public Affairs submitted a report to the House which incorporated a more aggressive public affairs program through the medias of radio, newspapers and television. A partial listing of subjects to be aired or printed could include DRG'S, Malpractice Crisis, Medicare and the Graying of America, Peer Review, CME, Medicare Assignment, etc. Following discussion, the House VOTED to refer the report back to the Council for further study.

Prospsed Amendments to the Bylaws

Introduced by the Council

(To be placed on the table for action at the next regular meeting of the House of Delegates)

SUBJECT: Delinquency

OBJECTIVE: To change the date of dues delinquency from August 1 to April 30. This will conform with the AMA delinquency date and also satisfy the requests from some of the counties which would like an earlier delinquency date.

PROPOSED AMENDMENT: Article XII Section 4—Delinquency

(Delete underlined words, add words in capitals.)

Par. 1—An Active Member is delinquent if his dues are not paid by August first APRIL THIRTIETH of the year for which dues are prescribed and shall forfeit his active membership in the Society if he fails to pay the delinquent dues within thirty days after notice of his delinquency has been mailed to his last known address by the Executive Director of The Society. Active Members of The Society who have been dropped from the active membership roll for nonpayment of dues cannot be reinstated until such indebtedness has been discharged, but such indebtness shall apply only to the one fiscal year of delinquency.

SUBJECT: Duties of the President

OBJECTIVE: TO MAKE IT POSSIBLE FOR THE PRESIDENT TO SERVE AS AN ADDITIONAL ALTERNATE DELEGATE TO THE AMA

PROPOSED AMENDMENT: Article VI
Section 8. Duties of the President

(Add words in capitals.)

The President shall be an ex-officio member of all committees. He shall appoint all committees not otherwise provided for in these Bylaws, subject to confirmation by the Council. He shall visit the component medical association. HE SHALL SERVE AS AN ADDITIONAL ALTERNATE DELEGATE TO THE AMA. He shall perform such other duties as the House of Delegates or the Council shall direct.

AWARDS
CSMS Past Service Awards to Officers and County Councilors
OFFICERS

Joseph C. Czarsty, M.D., Oakville Vice Speaker CSMS House of Delegates	1983-1984
Gioacchino S. Parrella, M.D., Milford Councilor-at-Large	1983-1984

COUNTY COUNCILORS

Hartford County

Arthur D. Keefe, M.D., East Hartford
Associate Councilor 1983-1984

New Haven County

Joseph C. Czarsty, M.D., Oakville Associate Councilor	1980-1984
Mehdi S. Eslami, M.D., Waterbury Councilor	1982-1984

IN MEMORIAM

BECK, EUGENE C., Yale University Medical School, 1926. Dr. Beck was a general surgeon in the Fairfield County area since 1931. He was a lieutenant commander in the U.S. Naval Reserve, 1943-44. Dr. Beck was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died November 20, 1984 at the age of 84.

BREWER, ALFRED E., New York University Medical School, 1941. Dr. Brewer was an internist in the Litchfield County area since 1945 until his retirement in 1979. He was an attending at Sharon Hospital and at Columbia Presbyterian Hospital in New York City for 30 years. Dr. Brewer was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died November 7, 1984 at the age of 69.

BURNS, DANIEL W., Georgetown, 1965. Dr. Burns was an ophthalmologist in the Hartford County area since 1970. He served in the U.S. Navy from 1967 through 1969. Dr. Burns was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died November 16, 1984 at the age of 44.

GRAY, PHILIP, Tulane University Medical School, 1937. Dr. Gray was a general practitioner in the Middlesex County area since 1959; and at the time of his death was retired. He served as an officer during the European theater during World War II. Dr. Gray was a member of the Middlesex County Medical Association and the Connecticut State Medical Society; died November 12, 1984 at the age of 70.

MACCREADY, WILLIAM H., Harvard Medical School, 1927. Dr. MacCready was a general practitioner in the Hartford County area since 1929. He served in the Canadian Army from 1916 through 1919. Dr. MacCready was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died November 16, 1984 at the age of 86.

MCDOWELL, ARTHUR V., Albany Medical College, 1952. Dr. McDowell was a general practitioner in the Middlesex area since 1953 and started the emergency room department at Middlesex Memorial Hospital in 1967. He was with the hospital until his retirement earlier this year. Dr. McDowell was a member of the Middlesex County Medical Association and the Connecticut State Medical Society; died October 27, 1984 at the age of 59.

MOONEY, SYDNEY, Tufts Medical School, 1927. Dr. Mooney was a gastroenterologist in the Fairfield County area since 1927. He was retired at the time of his death. Dr. Mooney was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 29, 1984 at the age of 80.

MULAIRE, VICTOR, J., Boston University School of Medicine, 1939. Dr. Mulaire was an urologist in the Fairfield County area since 1945. He was a retired lieutenant colonel, U.S. Army Reserves. Dr. Mulaire was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died November 20, 1984 at the age of 70.

SANTICCIOLI, ALDO, University of Bologna, Italy, 1940. Dr. Santiccioli was a psychiatrist in the New London County area since 1948. He was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 26, 1984 at the age of 70.

SEMI-ANNUAL REPORTS TO THE HOUSE OF DELEGATES OF THE CONNECTICUT STATE MEDICAL SOCIETY

November 15, 1984

Report of the Council

GUY W. VAN SYCKLE, M.D., CHAIRMAN

The Council has met four times since the Annual Meeting of the House of Delegates held May 9, 1984. All members of the House have received detailed copies of the minutes of each meeting (minutes of 10/17/84 meeting included with this Handbook). Therefore, this report is limited to those matters which are felt to merit special emphasis. At the conclusion of the report, as appendixes, there are published items of business which are transmitted by the Council to the House accompanied by recommendations of the Council. The number given to each of the appendixes is identical with the number of the related section of this report.

1. Professional Liability Program

At its June 6th meeting the Council was informed that CNA planned a liability premium increase averaging 40%. The Council then authorized the Committee on Professional Liability to evaluate the possibility of activating the CSMS captive insurance company.

At a special meeting of the Council on Wednesday, July 18th following the report of the Professional Liability Committee, the Council decided to immediately activate the Connecticut Medical Insurance Company (CMIC), enter into contract negotiations with American Health Systems (AHS) to implement and operate CMIC, and appoint an Ad Hoc Committee to interact with AHS personnel. The committee consisted of Drs. Joseph S. Sadowski, Chairman, Lawrence B. Ahrens, Sultan Ahamed, W. Raymond James, Kevin Dowling, Jerome K. Freedman and James P. Orphanos.

Despite the extremely short time frame and deteriorating reinsurance scene, the necessary reinsurance reserves were obtained and requirements of the Insurance Commissioner met. CMIC became operational on October 1, 1984 with 922 physician policy holders. The new company will write approximately $8 million in premiums and has $6.6 million in capital reserves. The success of this venture is directly related to the outstanding contributions made by the Ad Hoc Committee chaired by Dr. Sadowski, the CSMS staff, AHS personnel led by Mr. John Dorsett, and numerous physician leaders in all counties.

Dr. Kevin Dowling of Hartford, was elected President of the Connecticut Medical Insurance Company (CMIC) and Dr. Jerome K. Freedman of New Haven, President of Connecticut Medical Management, Inc. (CMMI).

The Council believes that the successful establishment of our own program is an important first step in stabilizing malpractice premiums in Connecticut.

2. Reports from Physicians Serving on State and Federal Agencies

Dr. Edward Kamens of Fairfield was appointed to the 14 member Task Force on the Prospective Payment Systems for Hospitals. He has reported regularly and recently submitted a summary report of the 12 weeks of negotiations concerning some 20 issues.

A DRG type system for All-Payers in Connecticut will begin with draft regulations, public hearings and rewriting to have a final version available to the Attorney General's office by January 4, 1985. Final approval is planned by April 15, 1985. Hospitals will utilize the regulations for preparation of their budgets effective on October 1, 1986.

Nationally, the fallout continues from the activities of the Congress and other health policy makers. A detailed summary of the actions of the 98th Congress has been included as a separate item. (Appendix Item No. 2)

3. House of Delegates Resolutions

At the annual meeting on May 9, 1984, the House of Delegates referred several resolutions and recommendations to the President and Council for evaluation and report concerning:

(a) The present methods for physician licensure in Connecticut; the credentialing process utilized by hospitals in Connecticut; the present method of communication among the states, the status of individuals practicing medicine, with or without a license, in or outside a hospital. (Appendix Item No. 3 (a))

(b) Physician reimbursement for in-hospital care of patients; prospective pricing systems; fee schedules for physicians; and All-Payers legislation. (Appendix Item No. 3 (b)) (Appendix Item No. 3 (b-1))

The reports on these subjects are attached to this report under the applicable appendix number.

4. **American Medical Association**

   (a) *Medicare Freeze*

   The AMA filed a legal challenge to the Medicare Amendments to the Deficit Reduction Act. These amendments instituted a fifteen month freeze on payment rates to physicians for services to Medicare patients. In addition, each physician was required to decide by October 1 whether to be a participating physician or a non-participating physician and accept certain penalties. The court did allow an additional two weeks for decision, but did not issue the desired injunction. The court did not address the issue of whether the Medicare fee freeze and other provisions of this Deficit Reduction Act are unconstitutional as contended by the AMA. The court also has not issued a final ruling on the AMA charge that the Department of Health and Human Services (HHS) violated the Administrative Procedures Act by not allowing time for public comments. The action of the AMA was endorsed by the Council.

   (b) *Bioethics Committees in Hospitals*

   A Connecticut resolution concerning the formation of Bioethics Committees in Hospitals was approved by the AMA House of Delegates. It was voted to refer this resolution to the CSMS House for approval.

5. **Hartford County Medical Association (HCMA) Resolution RE—Medicare**

   Following a meeting with the United Seniors for Action, a resolution was passed by the HCMA Board of Directors concerning the subject of Medicare assignment and submitted to the Council for approval and submissicn to the CSMS house of Delegates.

   RESOLVED: That the House of Delegates of the Connecticut State Medical Society urge its members to accept Medicare assignment for any Medicare patient who is unable to afford a physician's fee.

6. **Connecticut Peer Review Organization (CPRO)**

   CPRO has finally received federal designation as the Peer Review Organization of Connecticut. Drs. William A. Whalen, Jr., Andrew J. Canzonetti, Daniel W. Doctor and Mehdi S. Eslami are presently serving on the CPRO Board of Directors. Dr. Edward Kamens has been appointed Medical Director.

7. **1985 Budget**

   The budget has been reviewed line by line by the Council and the Council voted to approve the budget and transmit it to the House of Delegates with the Council's recommendation that the dues structure of $175.00 (no change) and budget be approved by the House of Delegates.

8. **Bylaw Amendment Re Date of Dues Delinquency**

   In order to bring uniformity with the AMA and within the state, it was voted to approve the recommendation that the CSMS Bylaws be amended to change the delinquency date from August 1 to April 30. In accordance with the Bylaws, the amendment is being placed on the table for action at the next regular meeting of the House of Delegates. The item appears under "New Business" in the Handbook.

9. **Tort Reform**

   A proposal was submitted by the New London County Medical Association concerning medical malpractice reform through the mechanisms of contractual arbitration and effective hospital and office peer review. The Council referred the subject to the Committee on Professional Liability and the Committee on Legislation for their combined study, review and recommendation to the Semi-Annual Meeting of the House of Delegates.

10. **Public Affairs**

    A resolution pertaining to a public affairs program was introduced by Dr. William A. Whalen, Jr., President-Elect, concerning a more aggressive public affairs program through the medias of radio and newspapers concerning DRG's, PRO's, Medicare participation, Malpractice and care of unemployed and needy. The resolution was referred to the Committee on Public Affairs for evaluation, proposals and specific cost estimates, and to report its findings to the House of Delegates. It is expected that the Committee will have a report in time for distribution at the House of Delegates meeting.

11. **Brain Death**

    The Council has charged the Judicial Committee to develop an educational communication concerning the recently passed "Definition of Death" legislation for distribution to members of the Society. At its meeting on October 24, 1984, the Judicial Committee has undertaken the preparation of an informational article on the new Brain Death Law (P.A. 84-261) for publication in the Journal and the Newsletter.

12. **CSMS Committee on Allied Medical Services (Connecticut Joint Practice Committee)**

    The Connecticut Joint Practice Committee submitted the following resolution which was approved by the Council:

    RESOLVED: That the Connecticut State Medical Society and the Connecticut Nurses' Association recommend and support efforts by the medical and nursing schools of this state to collaborate wherever possible in fostering understanding of the roles, skills and special knowledge of the two professions, one with the other.

13. Conclusion

As indicated in the opening paragraph, only matters that are thought to be of major importance were included in this report. The members of the House are urged to review the minutes of the meetings held since the Annual Meeting of the House of Delegates. As Chairman of the Council, I shall be happy to answer any questions about any other items recorded in the minutes of the Council. At this time, the Chairman would like to express his appreciation and thanks to all members of the Council and staff whose cooperation and assistance have been invaluable.

N.B.: Actions taken on the items in this report appear in "Summary of Proceedings of the House of Delegates" under "From the Executive Director's Office" in this issue of *Connecticut Medicine*.

APPENDIX ITEM NO. 2
98TH CONGRESS ADJOURNS

For health care providers the 98th Congress, which adjourned in early October, represents some of the greatest change in nearly 20 years. With enactment in 1983 of the Social Security Amendments (P.L. 98-21), hospitals moved from a Medicare reimbursement system based on costs to a prospective payment system (PPS) based on diagnosis related groups (DRGs). Passage of the Deficit Reduction Act of 1984 (P.L. 98-369) (DRA) further reduced Medicare payments to hospitals while increasing beneficiary costs. At the same time, DRA directly affected the physician community by imposing a controversial 15-month freeze on physician fees (a companion mandatory assignment measure was defeated) with new incentives to increase physician acceptance of assignment.

Legislative Winners

While budgetary reductions were the focus of both sessions, a number of laws were passed to improve health care access and delivery. Despite objections of the AMA, Baby Doe legislation (P.L. 98-457) was passed requiring states to establish new offices to monitor and regulate the delivery of medical care to handicapped newborn infants. Strong bipartisan support pushed through legislation raising the Medicare Hospice Care reimbursement rates. Passage of a generic drug law is expected to increase access to less expensive generic drug products while providing drug companies with a restoration of patent time lost during the lengthy FDA approval process. Organ transplant legislation passed providing government funds to expand organ procurement agencies and to establish a national registry of organ donors and those seeking organs.

The 98th Congress also managed to do what observers thought it could not—enact reauthorization legislation for more than a dozen major health programs including block grants, health education assistance, nurse training aid, categorical grants, and biomedical research. New ventures on medical technology assessment, disease prevention, arthritis, and nursing research were supported.

Legislative Losers

Failures in the health area were few and, most probably, temporary. Congress again failed to agree on health planning legislation but continued the current program for yet another year. Efforts to impose new sanctions on physicians who lose their licenses or are convicted of a felony or misdemeanor were caught up in Democratic infighting in the House. Republican Senators derailed another attempt to increase consumer access to information about health care costs and quality. An All-Payer Cost Containment proposal, sponsored by Senator Kennedy and Representative Gephardt was defeated but suceeded in gaining attention for a Democratic alternative to the Administration's "competition-based" health cost containment system strategy. It is detailed later in this report because of its severe implications for physicians and its possible re-introduction in next session. Election-year worries and opposition from the Reagan Administration and the AMA led to an overwhelming defeat for a bill that would have allowed the use of heroin as a painkiller for terminally ill cancer patients. In the area of medical malpractice, Representatives Gephardt and Moore introduced H.R. 5400—Alternative Medical Liability Act—to reform medical malpractice laws by urging states to eliminate awards for pain and suffering and punitive damages. Hearings were held and action is possible in 1985. AMA opposed the bill, because of the less sanguine implications of other sections of the bill, i.e.: it remains unclear how the provisions of H.R. 5400 will decrease the practice of defensive medicine as proponents say it will; difficulty involved with predicting the provider's likelihood to opt for the new compensation system, compounded by the ability of one provider to involve others in the compensation agreement, and by the fact that some patients are eligible for H.R. 5400's provisions and others are not; it is likely that the cost of professional liability insurance would increase because of the probability of offers on marginal claims not now pursued and the continued need for physicians to maintain existing coverage and potentially increased coverage to cover the new program; and finally litigation and legal expenses would increase due to involvement of courts in discovery procedures with respect to patient injuries and reviews of any compensation offer over $5,000.

Kennedy, Gephardt Announce All-Payer Hospital and Physician Plan

The "Medicare Solvency and Health Care Financing Reform Act of 1984," and popularly referred to as the Kennedy-Gephardt plan (S. 2424 and H.R. 4870) is designed to eradicate projected deficits in the Medicare Hospital Insurance trust fund while controlling the overall growth in the cost of health care for all consumers. Principal sponsors and supporters (labor and aging groups) of the bill did not expect action this year but hope to set stage for legislative push in 1985. The plan contains a strong emphasis on state-designed cost containment plans with a tight national plan as a backup. A base-year accounting period for all hospital and inpatient physician costs would be established by allowing states to inflate that amount by the annual increase in the marketbasket of goods and services plus one percent for new technology. This would cover inpatient services delivered to All-Payers. States would be required to design cost control systems to keep inpatient costs at or below those target amounts (Connecticut General Assembly enacted P.A. 84-315). Penalties would be imposed on providers in cases where costs exceeded the annual limits.

The proposal included incentive Medicaid payments to states that design their own cost control systems quickly. For states that cannot or will not put a cost control system in place, the plan would require hospitals and physicians to operate under a national DRG prospective payment system for hospital and doctor fees. One lump payment would be made to the hospital for each DRG and the hospital would pay the doctor. The national DRG system would include inpatient physician fees and capital payments. While based on the newly created Medicare DRG system, Kennedy and Gephardt go several steps further by covering all payers, physicians, and capital costs. Congress rejected these concepts. However, at the urging of the authors, it included requirements for study by the Health Care Financing Administration on Medicare's PPS model.

Physician costs would be added to the Medicare portion of the system by use of an average payment per DRG in each carrier area for the base year. That amount would be updated to 1985 (first year of the proposed program) by the national average increase in physician costs. That amount would be added to each existing DRG as a single lump payment to the hospital. A 3 year phase-in system combining national and local costs would be used. For private paying patients, doctors would be required to begin billing for all inpatient services through the hospital rather than directly to the patient. No restraints on those charges would be in place until the third year of the program. After the third year of the program, the Secretary of HHS would be directed to unify the Medicare and private physician payment system. The plan contains no new quality assurance mechanisms.

APPENDIX ITEM NO. 3(a)
Report Re: Resolution Referred by House of Delegates May 9, 1984

The Committee on Hospitals was charged by the Council to follow up on the resolution passed by the House of Delegates calling for CSMS to evaluate and report on the following aspects of physician credentialling:

1. The present methods for physician licensure in Connecticut.
2. The credentialling process used by Connecticut hospitals.
3. The present method of communicating among the states the status of individuals practicing medicine with or without a license, in or outside of the hospital setting.

The Committee submitted the following report:

1. Although there is some checking of the credentials of applicants for licensure, it was felt by the Committee on Hospitals that there should be more in depth investigation and that the Society should support adequate funding and staffing for the Bureau of Licensure to carry out this vital work.

2. Following a survey of the hospitals, the Committee reviewed the responses and found considerable variation in the credentialling process used by hospitals. Because of the disparate levels of investigation, the Committee recommended that a guideline checklist be recommended to hospital staffs that would include the following elements of documentation and verification outlined in Figure 1 on the following page.

It is clear that communication lines do exist and can be utilized by responsible parties for authorized purposes. It is also clear that such utilization can be increased, and that guidelines sharing the best of what is currently being done by the hospitals would be a valuable contribution to all concerned.

3. The Federation of State Medical Examining Boards maintains a computerized central repository of disciplinary actions and send monthly reports to its member Boards, key governmental agencies, and to the AMA Physician Masterfile. Although there is no legal mandate requiring Boards to report their disciplinary actions, voluntary reporting has improved dramatically in the past year, and reports have been received from every state and territorial jurisdiction. Utilization of the clearinghouse has also increased significantly, and direct-line computer access by member boards is now being contemplated. Medical Societies and hospital staffs can access to such data through the AMA Masterfile.

The Council has voted to approve the recommendations and submits the report to the House of Delegates, as charged by the House on May 9, 1984. (This report was promulgated to all elected Presidents of Hospital Medical Staffs and all Hospital Chief Executive Officers in November, 1984.)

Figure 1

Hospital Medical Staff Credentialling Process

CSMS GUIDELINE CHECKLIST

Elements of Documentation and Verification

Documentation	Verification
1. Education Training References Board Certification/Eligibility Previous Hospitals Medical Societies Licensure: Connecticut Other Jurisdictions	1. Physical Check Follow-up by Mail/Phone Check of Indirect References (2nd stage references) Contact for Conn. Licensure: Mr. John Boccaccio (566-5296) SDHS Physician Licensure Bureau
2. Derogatory Information AMA Masterfile State DEA's State & County Medical Societies	2. Confront applicant if not mentioned in application or interview
3. Photograph	3. Photo verification with previous jurisdiction
4. P.L. Insurance Coverage	4. Check where appropriate
5. Previous Impairment	5. Confirm recovery
6. Discern gaps in background	6. Verify explanation for gaps

APPENDIX ITEM NO. 3(b)

REPORT RE: Resolution Referred by House of Delegates May 9, 1984

In compliance with the request of the House of Delegates, the President of the Society appointed an Ad Hoc Committee to evaluate and report on the following:

1. The types and reimbursement of payment systems being considered for physicians.
2. The impact of these systems on the availability and quality of patient care in Connecticut.
3. The ethical, moral and financial implications of these systems.
4. The alternatives open to the profession in coping with or opposing these systems, including legislative action.
5. The institution of a system to monitor the effect of an All-Payer bill of the quality of patient care.

Following is the report submitted to the Council and is hereby submitted to the House of Delegates with an expanded version of the various physician reimbursement systems (Appendix Item No. 3 (b-1).

1. That CSMS inform its membership of the types of physician reimbursement and payment systems being considered by the Federal Government and other third party payers and that the staff keep the Council and members apprised of future developments.
2. That CSMS, in liaison with the AMA continue to monitor the new proposals for physician reimbursement for data to determine the effect on all aspects of medical care and medical ethics.
3. In order to deal effectively with these systems, CSMS encourage its members to be informed as individual physicians and as members of organized medicine; that CSMS develop constructive liaison with the executive and legislative branches of government and with business/industrial coalitions; that CSMS develop meaningful public relations programs; and that CSMS develop constructive legislative programs.
4. The CSMS Committee on Statewide Medical Planning will be given the temporary responsibility to monitor effects of the All-Payer bill on the quality of care.

Although opinions were expressed regarding the potential for a negative impact by these systems on the availability and quality of care, the consensus was that at present there was insufficient data for a determination at this time. This also applied to the ethical, moral and financial implications of these systems. A detailed memorandum outlining proposals now being discussed in Washington is attached as Appendix Item No. 3(b-1).

APPENDIX ITEM 3 (b-1)

Schemes for Physician Payment

HCFA Options: DRGs or RVS

The Social Security Amendments of 1983 (P.L. 98-21) require that:

> During fiscal year 1984, the Secretary shall begin collection of data necessary to compute the amount of physician charges attributable, by DRGs to physicians' services furnished to inpatients of hospitals whose discharges are classified within those groups. The Secretary shall include, in a report to Congress in 1985, recommendations on the advisability and feasibility of providing for determining the amount of payments for physicians services furnished to hospital inpatients based on the DRG type classification of the discharges of those inpatients, and legislative recommendations thereon.

The Deficit Reduction Act of 1984 (P.L. 98-369) requires that this report be submitted by July 1, 1985. When Congress mandated this work, there was considerable evidence that paying hospitals by DRGs would promote competition, improve efficiency, and establish control over Medicare's inpatient costs. Congress hoped that by extending DRGs to physician costs it would promote Prospective Payment Systems (PPS's) thus aligning the incentives of physicians with those of the hospitals.

The report which follows describes HCFA's progress in conceptualizing physician reimbursement by two reform issues – one based on relative value scales, and the other based on MD-DRGs. The discussion on RVS's presents options which cover the full spectrum of physician services. The discussion of reform based on MD-DRGs presents options which are aimed at controlling inpatient physician costs but apply only to inpatient services. However, HCFA has considered introducing both alternatives together, packaging of certain groups of services, and applying MDDRGs to non-attending physicians. There is also a brief description of capitation as an option for physician reimbursement.

Relative Value Scale Fee Reform (RVSFR)

The most straightforward reform for physician payment is creating a fee schedule based on a RVS. Within RVSFR is a creation of fee schedules to replace UCR payment levels, and includes policies to implement the schedules and encourage physicians to accept them, and a system to assure that Medicare's overall physician costs remain in a target range. RVSFR encompasses both a RVS and a set of multipliers for converting those relative values into dollars. Thus RVSFR determines relative prices and absolute total payments for any particular volume of services. HCFA's attraction to RVS is that RVS offers the potential to control the full range of physician services while PPS covers only inpatient services equal to half of Medicare physician expenditures. This is important since HCFA anticipates that surgicenters and outpatient procedures are, in combination with PPS, moving the center of cost growth to the outpatient sector. RVSFR promotes economic neutrality and therefore, contains no incentives for physicians to enter certain specialties, to locate in certain regions, or to perform certain procedures. Again, HCFA will attempt to eliminate all such perceived distortions which they see obstructing market mechanisms. Such a system HCFA states has the flexibility to take advantage of changes taking place outside the Medicare sector in states where there is vigorous competition for patients, whether or not involving PPO's, HMOs and IPAs. Several changes would occur under RVSFR to include coding reform. Definition of common procedures, especially office and hospital visits, would be given time ranges for each type of visit with some form of allowance for absolute or range for complexity. This would be included to slow code creep. A second major task would be to define components of services in a comprehensive way to minimize unbundling. A third option is to "collapse" the HCPCS Coding System from 6000 to perhaps 2000 codes.

RVS Concepts

HCFA is studying three different approaches to RVS; RVS based on current charges accepts the status quo and assume the adequacy of current version of market economy. RVS based on production cost are primarily regulatory and akin to the PPS model and RVS based on stimulated competition utilizes market mechanisms to reverse perceived anti-competitive patterns and practices. Undoubtedly, an RVS will emerge containing all three elements, and furthermore, will incorporate both short-term and long-term "target" relative values. Five organizations are actively involved in this area: the Institute of Medicine has embarked on a two year study; current legislation mandates an 18 month study of RVS by the Congressional office of Technology Assessment; the American Society of Internal Medicine is engaged in a study in internal medicine; the American College of Physicians and the American College of Surgeons have proposed a joint venture; and the AMA is exploring studies to carry out a HOD vote for steps to identify and correct imbalances between different types of procedures.

Summary RVFSR

HCFA sees RVFSR addressing many fundamental problems of rising fees and perverse incentives by creating a system whose fees are capped and whose incentives are increasingly neutral. HCFA indicates that the strategy should reduce inflation of physician costs by limiting earnings through a flexible mixture of regulation and competition (the relative value scale regulated, the multipliers set by competition). The hazard of RVSFR is that code creep, technological upgrading, and unbundling might outrun refinement of the coding system and result in substantial increases in the total volume of services.

MDDRGs Prospective Payment System for Physicians (PPSP)

HCFA states that the major issues in designing PPSP are setting rates, the problem of assignment, and the problem of who to pay:

1. *Setting DRG-Specific Rates:* For each DRG Medicare would calculate the average total allowable physician charge per admission during the index year and might be specific to the 18 regions used for PPS, DRG-specific physician payments could be based on historical allowable charges and/or on a system of competitive bids. In setting DRG-specific rates, HCFA believes it necessary to also define the package of service which would be included in the term "part of an inpatient episode." For surgical DRGs, and some others, a certain number of services or time period of service before admission and after discharge would be

considered inpatient care so far as the attending physician was concerned. HCFA says this approach recognizes existing practices while discouraging shifting costs from inpatient to outpatient services. However, HCFA does indicate that there appears to be insufficient professional consensus or empirical data to allow defining wide "service windows" (a period before and/or after hospitalization for purposes of reimbursement) for most non-surgical DRG's.

2. *The Problem of Assignment.* Medicare's current policy of allowing physicians to accept or reject assignment on a case-by-case basis would be extremely expensive under a DRG-based system. The net effect would be to increase overall physician payments in the range of 15-30%.
3. *Who-to-pay Question and Accumulating Credits for Service:* HCFA explores 3 options here; paying the medical staff, the hospital, and individual physicians. Although HCFA offers solutions to utilize the medical staff and individual physician concept, the agency quickly points out the negative aspects of such approaches by stating arguments relative to problems with mechanisms for handling the funds, and by stating that paying the doctor a DRG rate for each case and having him pay his own costs and the services of other physicians would put him at very high risk from unpredictable fluctuation in case severity (same for Depts). A system with such potential inequities would be unacceptable to Congress.

Paying the Hospital

The DRG physician payment would go to the hospital which would then decide how to disburse it. The hospital could use an IPA model or elect to contract with some or all physicians to pay them in other ways. There are, according to HCFA, three significant advantages to reimbursing hospitals directly:

1. Payments to hospitals would move the system toward *capitation* as more and more services are bundled into one payment unit;
2. The hospital would be able to distribute funds between physician services and other services to increase efficiency; and
3. The hospital could adjust its payments to physicians to persuade them to bring their patients to the hospital.

HCFA acknowledges that setting weights for physician DRGs poses substantial technical problems because of the lack of data and utilization of contemporary patterns as a basis for rate-setting appears inappropriate.

Problems of PPSP

HCFA says PPSP brings the incentives of physicians into close alignment with those of hospitals, thereby, significantly reducing a useful tension between physician and hospital which has protective values for both Medicare and patients. The most serious risks are that hospitals and physicians may collaborate in "gaming" the system, in shifting costs to uncontrolled areas, admission splitting, skimming, manipulation of diagnosis, and simply that physicians will admit their patients to hospitals where they receive a higher return on their bills.

The strengths and weaknesses of RVSFR and PPSP lead HCFA to other alternatives namely: combination of the two, applying MDDRGs to hospital care for supporting physicians, bundling of selected DRGs or services, and capitation.

MDDRGs for Supporting Physicians

PPSP should solve problems not addressed by RVS but the potential impact of PPSP on the behavior of attending physicians suggest risks to Medicare and beneficiares. HCFA suggests paying supporting physicians such as pathologists, radiologists, anesthesiologists, consultants, and non-resident surgical assistants under an MDDRG system, while developing a RVSFR which would apply to attending physicians and outpatient care.

Packaging Selected Activities

HCFA states that procedures performed by surgeons, cardiologists, radiologists and gastroenterologists lend themselves to being reimbursed as packages. This scheme amounts to introducing MDDRGs for a limited number of DRGs, either by PPSP or RVSFR.

Capitation

Capitation is certainly the purest and most attractive (to HCFA) approach to the entire problem of health care payment, and Medicare is moving vigorously to promote development of capitation systems in the future. Some technical changes in Medicare's capitation rules might promote growth of the problem slightly, but HCFA is not aware of any scheme which could substantially accelerate the process. The imponderables associated with making the system mandatory, the problem of obtaining discounts, the uncertainties surrounding Average Annual Per Capita Cost, and the effects of enrolling individuals who would never have joined a capitation system voluntarily, are so large as to be unacceptable to most commerical insurers if beneficiaries are allowed choice among plans.

Connecticut State Medical Society

1985 BUDGET

The House of Delegates approved the 1985 Budget and membership dues for 1985 remain at $175.00

Income:

Estimated Income from Dues (@$175)	$704,375
Estimated Income from Journal	54,000
Building Income	8,000
Interest & Dividends	69,000
Reimbursement, Collection of AMA Dues	7,000
Miscellaneous Income	1,000
	$843,375

Budget Allotments:

President of the Society (Honorarium)		$ 2,000
Chairman of the Council (Honorarium)		1,500
Council Expense		4,800
Delegates to AMA (8 Del., Pres., Pres-Elect)		24,850
Travel	$ 7,250	
Lodging	9,000	
Per Diem	3,600	
N.E. Hospital Hospitality Suite (AMA Mtgs)	5,000	
(Mtgs. Chicago & Washington, DC)	24,850	
Legal Counseling		8,000
Legislative Counseling		27,000
Legislative Activities		10,000
Employees' Pension Fund		42,000
Trustees' Administrators' Fees—Pension Fund		3,000
Premiums for Employees' Health Insurance Plans		20,500
Reserve for Contingencies		50,000
Annual & Semi-Annual Meetings		14,500
General Insurance		3,000
Public Information Program & Symposiums		12,000
David A. Grendon Memorial Fin. Aid Fund of CSMS		8,000
Committee Allotments, Dues, Etc.		18,875
Public Health	600	
Legislation	1,000	
Liaison Comm. Pharm. Assoc.	350	
Cancer Coordinating Committee	500	
Mental Health	100	
Hospital Committee	150	
Third Party Payments	200	
AMA-ERF Campaign	300	
Perinatal Morbidity & Mortality	250	
Emergency Medical Service	100	
Insurance—CSMS Programs	100	
CME Comm. & Accreditation Programs	1,000	
Coop. Comm. Med. Schools of Conn.	200	
Public Affairs	400	

Budget Allotments: (Continued)

Council N.E. State Med. Soc. (Dues)	175	
Comm. Program Scientific Assembly	200	
Judicial Committee	500	
Liaison Comm.—Dept. Income Maint.	150	
Forum for Medical Affairs (Dues)	150	
Professional Liability	500	
Statewide Medical Planning	500	
Drug Abuse Educational Program	500	
Maternal Morbidity & Mortality	50	
Allied Medical Services	600	
Medical Aspects of Sports	200	
Auxiliary to CSMS	3,000	
Student Section	3,500	
Resident Section	3,500	
Miscellaneous Committees	100	
	$18,875	
		$250,025

Treasurer's Budget:

Printing & Postage (Coll. of Society Dues)	1,100
Printing & Postage (Coll. of AMA Dues)	600
Certified Accountants (Annual Audit)	1,400
Computer Services (Financial Reports)	700
Miscellaneous	100
	$3,900

Executive Office Budget:

Personnel		$283,487
Pension for Mrs. Creighton Barker (6/23/60)		3,000
Office Operation:		43,850
Staff Travel & Misc. Expenses	$11,000	
Office Supplies	800	
Maintenance of Office Equipment	1,200	
Printing & Postage	8,000	
Telephone Tolls & Telegrams	1,800	
CSMS Newsletters	10,000	
Sportsmed Publication	5,500	
Subscriptions	300	
News Clipping Service	600	
Addressograph Service	350	
Automobile Lease	4,200	
Miscellaneous	100	
	$43,850	

Provision for Social Security Taxes		17,947
Provision for Unemployment Taxes		2,195
		$350,479
Journal Budget:		
Personnel		$ 45,038
Manufacturing Cost & Distribution		143,100
Printing Journal	$128,000	
Roster & Dist.	9,000	
Postage & Handling	11,200	
Reprints	3,900	
	$143,100	
Office Operation		6,675
Printing & Postage	$2,500	
Office Supplies	600	
Telephone Tolls & Telegrams	900	
Sales Tax	275	
Editorial Board Meetings	200	
Editor's Travel (250 mi. radius)	925	
Maintenance of Office Equipment	350	
Subscriptions	300	
Copyrights	–	
Libel/Slander Insurance	500	
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Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

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Jan. '85. Age 29. AB elig. MD, Universidad del Caribe, Cayey, Puerto Rico; Int. and Res., St. Vincent's Medical Center. Prefers group or associate type practice. Write, Dominic F. Mazzocchi, M.D., 1231 East 89th St., Brooklyn, NY 11236.

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UROLOGY

July '85. Age 34. Nat'l bds. AB elig. MD, Cornell University Medical College, New York, NY; Int. and Res., Medical College of Virginia Hospitals. Prefers solo, group or associate type practice in a medium-sized community. Write, Richard Tushman, M.D., 519 Vantage Place, Richmond, VA 23236.

Endomyocardial Biopsy

JAMES E. DOUGHERTY, M.D., ALFREDO F. NINO, M.D., MICHAEL A. ROSSI, M.D.,
HENRY B.C. LOW, M.D., MARTIN J. BERMAN, M.D.
AND ROBERT T. SCHWEIZER, M.D.

ABSTRACT— Right ventricular endomyocardial biopsy is an important diagnostic tool in the practice of clinical cardiology. The technique is well accepted in the management of cardiac transplant recipients and in the assessment of cardiotoxicity secondary to doxorubicin and related chemotherapeutic agents. Present techniques permit safe and rapid procurement of biopsy specimens which can be a valuable adjunct in the diagnosis of other cardiac problems, including cardiomyopathies, myocarditis and arrhythmia evaluation. Our experience with the first twenty biopsy procedures at Hartford Hospital confirms the importance and safety of endomyocardial biopsy.

The concept of cardiac biopsy has long been appreciated, but was abandoned secondary to lack of an acceptably safe technique. Early biopsy methods included a percutaneous needle approach to the left ventricle and an intracardiac needle biopsy of the interventricular septum.[1,2] Neither of these methods gained widespread acceptance because of the associated morbidity, mortality and inherent invasiveness of the techniques.

Transvenous right ventricular endomyocardial biopsy was first described in 1962 by Konno and Sakakibora.[3] A peripheral vein cutdown was performed through which a catheter was advanced to either ventricle where small movable jaws removed a 1-3mm specimen of tissue. The procedure proved to be safe and without serious complications. However, the technical difficulties associated with the bioptome and the size of the catheter caused the technique not to gain extensive acceptance outside Japan.

By 1970 cardiac biopsy had essentially been abandoned in the United States as a clinical procedure.[4] In the early 1970's, however, attempts at percutaneous biopsy were again made concurrently in the United Kingdom and at the Stanford University Medical Center in California.[5,6] The British technique used a modification of the Olympus fiberoptic bronchoscope biopsy forceps called the King's endomyocardial bioptome. This method improved on the original Japanese technique with increased ease of biopsy and acceptable morbidity although specimens were smaller. The King's endomyocardial bioptome is presently widely used in Europe.[7] At Stanford University, Caves and associates developed a modified Konno bioptome in response to the need for a diagnostic tool to monitor allograft rejection in the cardiac transplantation program. The Caves-Schultz-Stanford bioptome, as it is presently known, has been further modified and currently is the most frequently utilized technique in North America.[8] This bioptome is more flexible than the original Konno instrument and can be introduced percutaneously under local anesthesia.

The Caves technique carries an acceptably low risk of morbidity and virtually no mortality. At Stanford University, over 4000 procedures have been performed with no deaths and a major morbidity of less than 1%.[8] The most common problem is occasional difficulty obtaining internal jugular access. The major complications are similar to temporary pacemaker insertion which include cardiac perforation with tamponade or sustained ventricular arrhythmias. Epicardial fat in the biopsy specimen is not uncommon, but in the absence of symptoms is not of major importance.

JAMES E. DOUGHERTY, M.D., Assistant, Department of Medicine, Division of Cardiology; ALFREDO F. NINO, M.D., Associate, Department of Medicine, Division of Cardiology; MICHAEL A. ROSSI, M.D., Senior, Department of Medicine, Division of Cardiology; HENRY B.C. LOW, M.D., Senior, Department of Surgery; MARTIN J. BERMAN, M.D., Senior, Department of Pathology; ROBERT T. SCHWEIZER, M.D., Senior, Department of Surgery; all of the Hartford Hospital, Hartford, CT.

Reprint requests to: 85 Jefferson St., Hartford, CT 06106 (Dr. Dougherty).

Methods and Materials

The technique used at Hartford Hospital is patterned after that of the Stanford University Medical Center using the Caves-Schultz-Stanford bioptome (Figure 1).[6,8] The right internal jugular vein access is preferred although the left subclavian vein has been used. Cardiac biopsy can be performed on either an in-patient or day-patient status. The procedure is performed in the fluoroscopy suite and requires approximately 15 minutes and no special monitoring post-biopsy. Cannulation of the right internal jugular vein is performed in the standard manner with an 8.5 F catheter sheath system. After vein cannulation, the bioptome is advanced under electrocardiographic and fluoroscopic guidance to the right ventricular cavity. The patient should not feel pain. Three to five specimens are obtained, each measuring one to three millimeters in size. Specimens are fixed in solution of 10% phosphate buffered formalin prior to staining. All specimens are stained with Hematoxylin & Eosin and Masson's trichrome. Additional special stains are used when indicated (Table 1). Samples are reviewed by a cardiac pathologist utilizing light and/or electron microscopy.

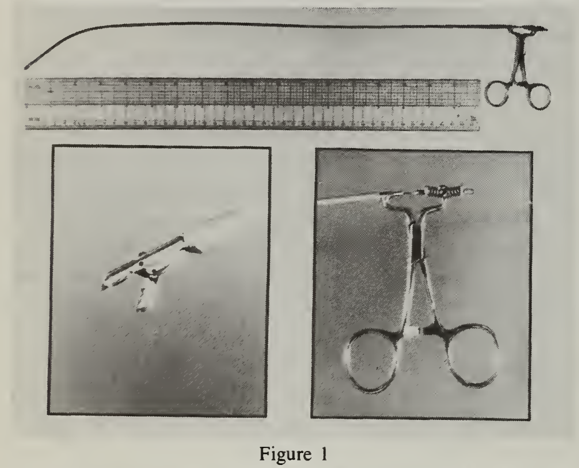

Figure 1
Caves-Schultz-Stanford bioptome as presently used for endomyocardial biopsy.

Table 1
SUMMARY OF COMMON STAINS AND ASSOCIATED DIAGNOSIS

Tissue, Problem	*Stains*	*Diseases*
Myocytes	H&E, Masson's trichrome	Doxorubicin cardiotoxicity
Lymphocyte activation	Methyl green-pyronine	Allograft rejection
Fibrosis	Masson's trichrome	Cardiomyopathy
Amyloid Protein	Congo Red	Amyloidosis
Granuloma	H&E	Sarcoidosis
Iron Deposition	Prussian blue	Hemochromatosis
Lymphocytes	H&E	Myocarditis

Results

Twenty biopsy procedures have been performed as summarized in Table 2. Biopsies were performed on fourteen different patients with one patient having had multiple procedures on a serial basis. Approximately 80 individual biopsies were performed. The only complication was a neck hematoma in one patient. Two biopsies contained epicardial fat, however, neither patient experienced any adverse clinical sequelae. The value of these biopsies is illustrated by two case reports.

Case Reports

Case 1 – A 55-year-old man was transferred to Hartford Hospital in 1983 with a history of prior myocardial infarctions, recurrent ventricular arrhythmias and severe congestive heart failure. The patient's clinical status was stabilized. He underwent invasive and non-invasive evaluation leading to the diagnosis of ischemic cardiomyopathy not amenable to conventional surgery. The patient remained NYHA Class IV requiring aggressive medical attention and in January, 1984, he underwent orthotopic cardiac transplantation at the University of Pittsburgh. He subsequently has returned to the greater Hartford area and receives followup care, including serial endomyocardial biopsies at Hartford Hospital. He remains NYHA Class I since surgery and is clinically doing well.

This patient has now undergone endomyocardial biopsy seven times without major complication and the histological findings have been the basis for ongoing adjustment of immunosuppressive medication. Mild degrees of asymptomatic rejection (Figure 2) which have not required treatment as well as one episode of moderate rejection (Figure 3) have been found. In the latter situation myocyte necrosis was seen histologically without associated clinical changes, thereby allowing for early immunosuppressive treatment. The case demonstrates the value of cardiac transplantation in selected cases and the concomitant need for serial endomyocardial biopsies to monitor allograft rejection.

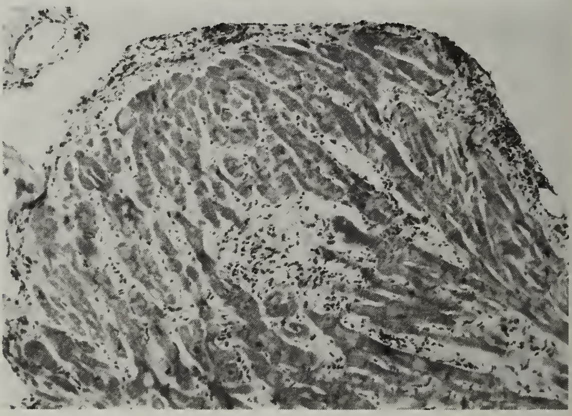

Figure 2
Mild Cardiac rejection: Note subendocardial and perivascular infiltrates with associated interstitial edema (H&E × 160).

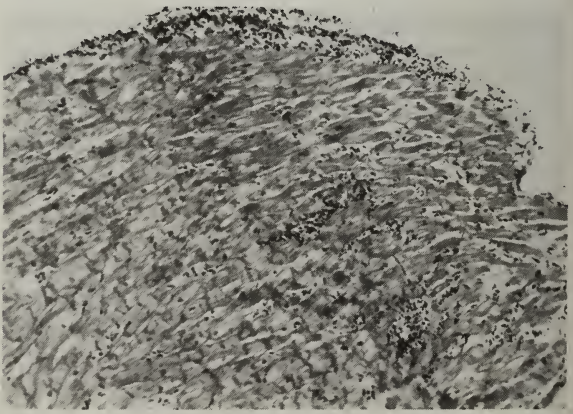

Figure 3
Moderate rejection: Note increased density of perivascular, subendocardial and interstitial infiltrates associated with early myocyte necrosis with contraction band changes in myocytes (H&E × 160).

Table 2
HARTFORD HOSPITAL BIOPSY EXPERIENCE

	Age	*Date*	*Indications*	*Diagnosis*	*Complications*
1.	65	4/83	cardiomyopathy	idiopathic cardiomyopathy	none
2.	39	8/83	cardiomyopathy, r/o myocarditis	fibrotic cardiomyopathy	none
3.	34	10/83	transplantation evaluation	congestive cardiomyopathy	none
4.	64	1/84	cardiomyopathy	focal interstitial fibrosis	none
5.	65	2/84	cardiomyopathy	amyloid	none
6.	51	2/84	transplantation evaluation	focal hypertrophy	none
7.	56	3/84	post-transplant follow-up	mild rejection	neck hematoma, asymptomatic
8.	56	3/84	post-transplant follow-up	mild-moderate rejection	none
9.	48	4/84	cardiomyopathy	normal	none
10.	56	4/84	post-transplant follow-up	mild rejection	none
11.	56	4/84	post-transplant follow-up	mild rejection	none
12.	46	4/84	transplantation evaluation	idiopathic cardiomyopathy	none
13.	56	5/84	post-transplant follow-up	mild rejection	none
14.	31	5/84	post-partum cardiomyopathy	no inflammatory or fibrotic changes	none
15.	50	5/84	cardiomyopathy, multiple myeloma Pre-Adriamycin®	interstitial fibrosis, focal amyloid	none
16.	30	5/84	cardiomyopathy	early cardiomyopathy changes, no fibrosis	none
17.	56	6/84	post-transplant follow-up	mild-moderate rejection, focal myocyte necrosis	none
18.	46	6/84	transplantation evaluation	mild cardiomyopathy	none
19.	56	6/84	post-transplant follow-up	mild rejection, improved	none
20.	61	7/84	hemochromatosis, cardiomyopathy	fibrotic cardiomyopathy	none

Case 2—A 65-year-old woman was evaluated in 1983 for signs and symptoms of mild congestive heart failure. Studies at that time demonstrated normal coronary anatomy, normal left ventricular size and contractility and mild ventricular hypertrophy. Her background history included adult onset diabetes mellitus, hypertension and multiple myeloma. The patient's clinical course deteriorated requiring repeat hospitalization and dobutamine infusion for ionotropic support. This resulted in dramatic improvement. She then underwent endomyocardial biopsy for diagnostic purposes and this demonstrated amyloid deposition.

The etiology of the patients heart failure had been unclear and biopsy allowed for appropriate clinical focus on this specific restrictive cardiomyopathy. Most cases of cardiac amyloidosis show diffuse endocardial infiltration, making the endomyocardial biopsy particularly good for establishing the diagnosis. The pathological findings of diffuse congo red birefringence establishes the diagnosis (Figure 4). This case points out the potential role for endomyocardial biopsy from both a diagnostic and prognostic point of view.

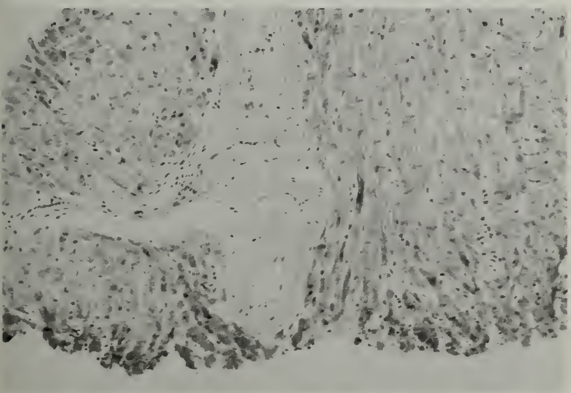

Figure 4
Cardiac amyloid: Intramyocardial small arterial vessels with replacement of medial coat by opaque homogenous non-fibrillar amyloid deposits (H&E × 160).

Discussion

The role of right ventricular endomyocardial biopsy has been well documented in the management of cardiac allograft rejection and for the assessment of doxorubicin (Adriamycin ^{R}) cardiotoxicity.[9-13] Both clinical and investigational applications for cardiac biopsy continue to evolve since the development of the transvenous technique by Sakakibora and Konno.[3] The safety and ready accessibility of endomyocardial biopsy to obtain cardiac tissue has resulted in investigating new indications. Clinical situations such as cardiomyopathy, myocarditis, unexplained heart failure, and dysrhythmia may benefit from endomyocardial biopsy, but these indications for biopsy are presently unclear.

The greatest application for endomyocardial biopsy is in cardiac transplantation, which continues to grow as a clinical and therapeutic reality. The diagnosis of acute graft rejection following transplantation no longer relies on electrocardiographic voltage and associated clinical parameters. Instead, endomyocardial biopsy has totally replaced these prior techniques for the early recognition and diagnosis of rejection.[9-11] Frequent endomyocardial biopsies are well tolerated by transplant patients. The results obtained become the basis for dosage of anti-rejection medication and future biopsy intervals. This technique has resulted in improved transplantation survival as well as providing an objective basis for reduced immunosuppression therapy with concomitant lowered morbidity and mortality. The salient morphological features are recognized on Hematoxylin & Eosin and Masson's trichrome stains as previously seen in Figures 2 and 3. Our experience has shown this to be a reproducable and independently verifiable basis of monitoring rejection. The universal classification of acute cardiac rejection is largely based on the Stanford experience.[10] Biopsy specimens are examined for evidence and extent of perivascular and endocardial infiltrates, myocyte necrosis and fibrosis. The specimens are then graded as mild, moderate or severe.

Another important use of endomyocardial biopsy is in doxorubicin (Adriamycin^{R}) therapy. Doxorubicin remains a potent and effective chemotherapeutic agent used in a wide spectrum of both hematological and solid malignancies. Its use is limited by the development of cardiotoxicity in certain patients, manifested as an insidious congestive cardiomyopathy which is generally not reversible. It is now well known that a cumulative dose of less than 500-550 mg/m2 results in an acceptably low incidence of this side effect. Unfortunately, restriction of doxorubicin to that dose level means discontinuation of a potentially life saving treatment. To aid in the detection of which subset of patients may be at increased risk for cardiotoxicity, a number of non-invasive studies including nuclear ventriculography have been investigated.[14] Radionuclide ejection fractions are sensitive and acceptably reliable, but do not allow for accurate differentation of heart failure from causes other than doxorubicin. Transvenous endomyocardial biopsy allows for a semi-quantitative and objective scoring of ultrastructure changes secondary to doxorubicin to aid in making this determination.[12,13] This technique is reserved for patients with risk factors which include prior mediastinal radiation, age greater than 70, underlying heart disease or a history of hypertension. In this group, the incidence of heart failure was 17% in the Stanford experience when analysed retrospectively, a figure which can approach zero by selecting which patients are at risk for heart failure with ventricular biopsy.[4] The grading system requires ten blocks to be examined and the three to five with the most prominent changes being examined by the electron microscopist. The histological changes are seen on electron microscopy and are of two main types—myofibrillar loss and T-tubular swelling or vacuolization.

Billingham and associates consider endomyocardial biopsy to be of value in areas far beyond those already discussed.[15] These include the diagnosis and follow-up of myocarditis, primary cardiomyopathies, specific muscle disease, diagnosis of restrictive *vs.* constrictive heart disease, and in the management of idiopathic arrhythmias. In myocarditis, endomyocardial biopsy provides an objective basis for consideration of immunosuppressive treatment.[16-19] However, there is currently little information that immunosuppression in this setting is effective in improving cardiac performance. Finally, endomyocardial biopsy can be of value in hospitalized patients with heart failure as an adjunct in the detection and management of specific myocardial disorders. For example, cardiac amyloidosis as the basis for restrictive heart failure can be diagnosed and thereby provide useful prognostic as well as therapeutic insights as outlined in the case discussion.[20,21]

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Sleep Apnea Contributing to Respiratory Failure in the Mounier-Kuhn Syndrome

JOHN J. VOTTO, D.O., DIANNE TRUEB, R.R.T. AND
JAMES R. MCCORMICK, M.D., F.C.C.P.

ABSTRACT—Tracheobronchiomegaly (Mounier-Kuhn syndrome) is a rare disorder characterized by generalized abnormal dilatation of the trachea and proximal airways. Most patients have developed recurrent pulmonary infections, changes of destructive bronchiectasis and obstructive airways disease, often eventuating in respiratory failure. We have described another individual with tracheobronchiomegaly associated with obstructive sleep apnea syndrome. He had no evidence of obstructive airways disease and has had no further evidence of cor pulmonale since beginning nocturnal oxygen therapy four years ago. We believe that repetitive apneas during sleep contributed more to his episode of respiratory failure than did the Mounier-Kuhn syndrome. However, flaccidity of the large airways and perhaps the oropharynx may have favored the generation of more negative intrapharyngeal pressures with inspiration during sleep, resulting in narrowing of the upper airway and obstructive apneas or hypopneas.

Introduction

The Mounier-Kuhn syndrome (tracheobronchiomegaly) is characterized by generalized abnormal dilatation of the trachea and major bronchi. Although the pathogenesis of the lesion is unknown, it is widely believed to represent a congenital, perhaps hereditary,[1] defect which often results in recurrent bronchopulmonary infection, presumably due to ineffectual clearance of secretions. This anomaly is rare; less than 90 cases have been reported since its description in 1932. Most patients have been male and a disproportionate number were black. The lesion is characterized bronchographically or bronchoscopically by marked enlargement of the proximal airways, sometimes accompanied by diverticula formed of redundant folds of the membranous portion of the trachea and mainstem bronchi.

In this report we describe a patient with tracheobronchiomegaly who developed chronic respiratory failure and cor pulmonale associated with obstructive sleep apnea.

Few patients have been asymptomatic. Most have had symptoms and roentgenographic findings of saccular bronchiectasis which often progressed to chronic cardiorespiratory failure and death.

Case Report

A 41-year-old black male smoker had been in good health until 1963 (age 22) when he developed pneumonia following exposure to tear gas at Navy boot camp. He was hospitalized for 18 days with good recovery. Approximately six weeks later, he developed "double" pneumonia and was hospitalized at Balboa Naval Hospital. From then until 1972, the patient related at least yearly episodes of pneumonia or bronchitis. In 1972 he was admitted to the Newington V.A. Hospital for pneumonia. A chest x-ray (Figure 1) on admission demonstrated a widened trachea, and subsequent tomograms (Figure 2) and bronchography (Figure 3) confirmed tremendous enlargement of the trachea (48 mm), both mainstem bronchi (right-32 mm, left-30 mm) and saccular bronchiectasis. The mean values for normals according to Katz [2] are: Trachea-20.2 mm, right main bronchus-16.0 mm, left main bronchus-14.5 mm. At that time a diagnosis of Mounier-Kuhn syndrome was made.

The patient continued to have at least yearly exacerbations of his lung disease, each time requiring vigorous postural drainage, antibiotics and bronchodilators for resolution. In August, 1979, he was admitted again to our hospital, this time in respiratory failure with hypercapnia requiring intubation and mechanical ventilation.

JOHN J. VOTTO, D.O., Assistant Professor of Medicine, University of Connecticut Health Center; Attending Physician, V.A. Medical Center, Newington, CT. DIANNE TRUEB, R.R.T., Director of Pulmonary Laboratory, V.A. Medical Center, Newington. JAMES R. MCCORMICK, M.D., F.C.C.P., Associate Professor of Medicine, Medical College of Georgia; formerly Chief, Pulmonary Medicine, V.A. Medical Center, Newington.

Physical examination on admission revealed a somnolent, obese black man who was markedly dyspneic. Because of a short, thick neck, the jugular venous pressure was difficult to assess. Examination of the lungs revealed there were rales at both lung bases and tubular breath sounds at the right base. There was an accentuated pulmonic component of the second heart sound and an S_3 which increased in intensity with inspiration. The abdomen was obese with no organomegaly. There was no pretibial edema and no clubbing. A cardiogram was consistent with right ventricular hypertrophy. Arterial blood gases on admission while breathing room air were: pH 7.35, pCO_2 75, pO_2 41. A chest x-ray demonstrated a right pleural effusion; there was no evidence of a concurrent pneumonia. Respiratory failure responded to improved oxygenation during mechanical ventilation and diuretic therapy.

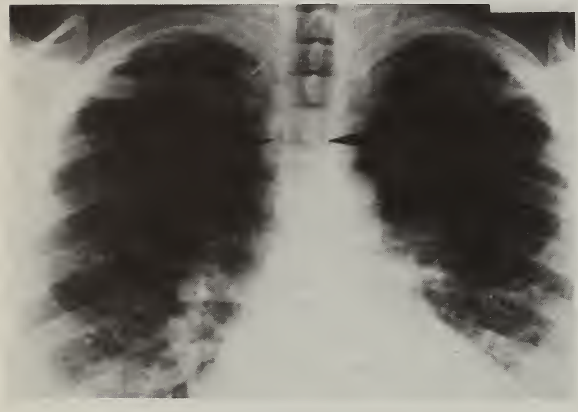

Figure 1
Chest roentgenogram (PA) demonstrating a markedly widened tracheal shadow (arrows).

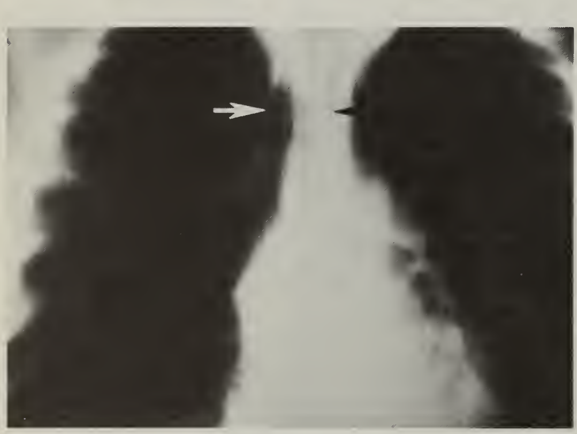

Figure 2
PA tomogram confirming abnormal tracheal enlargement.

After his recovery, he related increasing daytime somnolence, difficulty concentrating, and a modest weight gain over the preceding year (current weight 235 lbs; height 68″). On review of old records, significant daytime somnolence had initially been noted in 1974. In fact, he had fallen asleep during conversations and while waiting to be seen in the clinic. Pulmonary function tests done after recovery showed mild restriction but no obstruction and a normal diffusing capacity. The expiratory flow-volume curve consistently demonstrated repetitive oscillations throughout the maneuver (Figure 4). Subsequent radionuclide cineangiography showed right ventricular enlargement with a right ventricular ejection fraction of 32%. Left ventricular chamber size and ejection fraction were normal.

Sleep apnea syndrome was suspected and polysomnography was carried out, monitoring EEG, oxygen saturation, EKG, chest wall motion and airflow at nose and mouth. This revealed many episodes (average 109 per hour) of obstructive and mixed apneas, usually associated with arterial desaturation from a resting level of 90 to as low as 78% (Figure 5). Oxygen supplementation during sleep eliminated the arterial desaturation with minimal prolongation of the apneic periods.

The patient refused tracheostomy, weight reduction therapy and further invasive studies. However, he has had improvement in exercise tolerance, resolution of daytime somnolence, no recurrence of right heart failure and, in fact, has worked in a supervisory position since beginning nighttime oxygen supplementation four years ago.

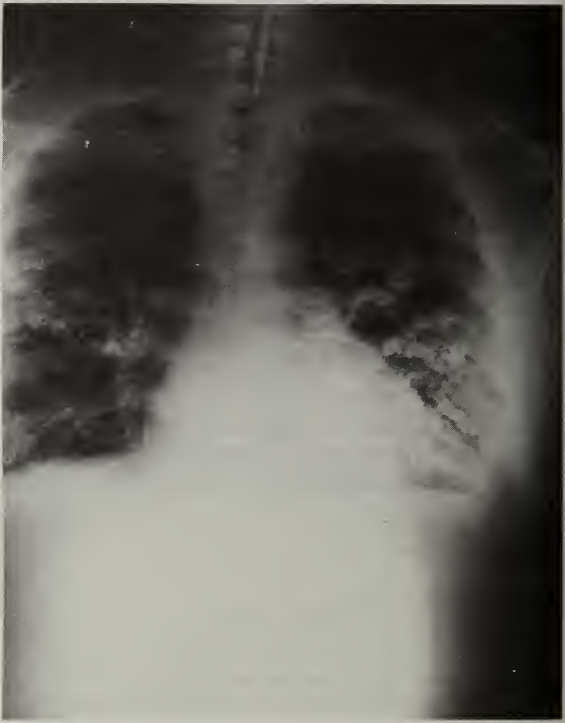

Figure 3
The bronchogram clearly shows the marked dilatation of the major airways and saccular bronchiectasis.

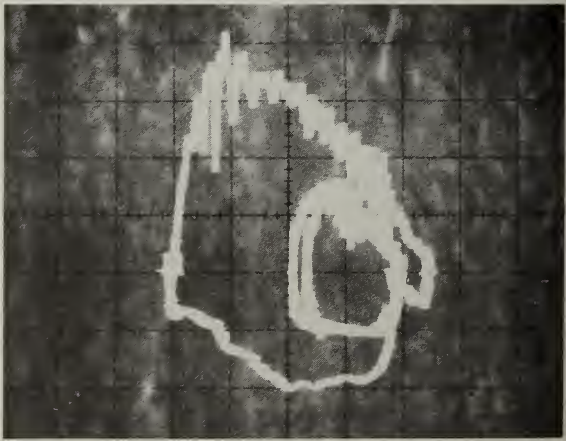

Figure 4
Typical "saw-tooth" oscillations are present on the expiratory limb of the flow-volume loop.

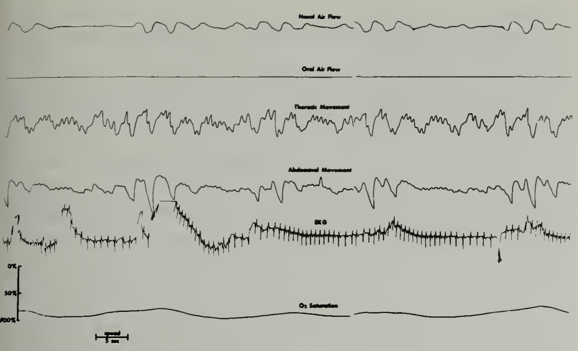

Figure 5
Polysomnography demonstrates abrupt cessation of nasal airflow with persistent movements of the chest wall and abdomen indicating obstructive apnea. Increased abdominal muscular activity is associated with a resolution of ventilation and was usually accompanied by a loud stentorous sound from the nasopharynx.

Discussion

We have described another individual with tracheobronchiomegaly. The rarity of this disorder precludes any clear understanding of its natural history but its frequency has been estimated at no more than 1 in 200 patients with bronchiectasis discovered on bronchography,[3] and it may be more common in blacks. The few deaths reported appear to be directly related to recurrent bronchopulmonary infections, as is the morbidity in most cases.[4,7,8] Functional impairment, characterized by airflow limitation during expiration, has often been described and probably results from changes of destructive bronchiectasis and inspissation of secretions rather than from dilatation and flaccidity of the proximal airways. The cause of recurrent infections is unknown but reduced effectiveness of mucociliary clearance in dilated proximal airways must be considered and deserves investigation. Our patient clearly had bronchiectasis but normal flow rates, probably reflecting normal upstream resistance and alveolar elastic recoil pressure.

Although the cause is unknown and no specific treatment is available, early recognition of the presence of tracheobronchiomegaly should lead to the institution of a therapeutic regimen aimed at preventing and appropriately treating respiratory tract infections. In our patient we believe that repetitive apneas and nocturnal oxygen desaturation contributed more to the development of cor pulmonale and respiratory and cardiac failure than did recurrent infections.[5,6] Support for this conclusion lies in the significant improvement afforded by chronic nocturnal oxygen supplementation alone. Since most of the sequelae of recurrent significant apneas or hypopneas during sleep can be related to episodic hypoxemia, its salutary effect was not unexpected. The effects of nocturnal oxygen therapy on blood gases and hemodynamics have been studied in very few patients with sleep apnea syndrome.[7] Although hypoxemia was averted, the duration of the apneic episodes and degree of hypercapnia and acidosis increased.[7] Our patient underwent a trial of oxygen therapy during his initial sleep study. Although oxygen saturation remained $>90\%$ by ear oximetry, we did not measure arterial pCO_2 or pH and thus cannot be sure that respiratory acidosis was not accentuated. The fact that apnea duration did not increase appreciably, however, suggests that significant hypercapnia could not have occurred. The reasons for the difference in response to oxygen of our patient and those of the previous report[7] are not clear. Recently Kearley et al,[8] have demonstrated that patients with chronic obstructive lung disease and sleep-disordered breathing (apneas and hypopneas) could be protected from desaturation by low flow nocturnal oxygen therapy without risk of prolonging the apneic episodes. Clearly there are differences in individual responses to prevention of hypoxemia, perhaps reflecting different mechanisms of recovery from an apneic episode.

There is no evidence that the Mounier-Kuhn syndrome and this man's obstructive apneas are related. He certainly exhibited a physiognomy consistent with other patients who develop obstructive apneas during sleep.[6] Flaccidity of the oropharynx has not been reported in tracheobronchiomegaly, but, if present, could contribute to collapse of the oropharyngeal musculature during inspiration. Of interest, our patient did exhibit "saw-tooth" oscillations of the expiratory limb of his flow-volume curve, a finding reported to be characteristic of obstructive sleep apnea syndrome.[9] Fluttering of the tissues of the oropharynx has been observed in these patients during quiet breathing, presumably reflecting the generation of variable degrees of negative pressure in a narrowed, flaccid upper airway. It would be interesting to postulate that apposition of the walls of the trachea and major bronchi during expiration, which has been observed in several individuals with tracheobronchiomegaly, necessitated more negative intrapleural pressure during inspiration to re-open the airways, thus favoring narrowing of the oropharynx and the development of upper airway obstruction.[10,11] Further studies of this man and others might prove interesting in testing this hypothesis.

The demonstrated coexistence of tracheobronchiomegaly and sleep apnea syndrome in this case serves to remind us that in evaluating patients with this disorder we should search for other treatable problems which may contribute to the development of respiratory failure. Should a history consistent with sleep apnea syndrome be elicited, polysomnographic studies including measurement of esophageal pressure and perhaps cineradiography of the intra- and extrathoracic airways may be indicated.

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Monoclonal Antibodies in Clinical Practice

WILLIAM CIEPLINSKI, M.D.

ABSTRACT—Monoclonal antibody technology has provided the capability to produce large quantities of single specific antibodies in a reproducible fashion. The technology involves fusion of spleen cells from an immunized animal to malignant mouse myeloma cells. Monoclonal antibodies are being used in clinical practice to supplement and improve histopathological diagnosis. The antibodies help to classify cells of different tissues through the recognition of specific surface antigens. One important application has been the recognition of T cell subsets, Helper and Suppressor/Cytotoxic. Monoclonal antibodies against T cells subsets have been used therapeutically to treat transplantation rejection in kidney allograft. In Oncology, possible tumor specific antigens may serve as targets for monoclonal antibodies alone or coupled to cytotoxic drugs or toxins. Anti-idiotypic monoclonal antibodies may serve also as treatment for B cell neoplasias carrying the idiotype in their surface. Another possible use is as antigens for immunization instead of more potentially dangerous primary antigens.

The use of antibodies in clinical medicine and medical research goes back many years. A large number of diagnostic tests are based on immune reactions and immune antisera have been used in the therapy of a number of diseases. Before the antibiotic era, serotherapy using immune antisera from convalescent patients and immunized animals was used at times for the treatment of infectious bacterial diseases. Immune sera are still used for the treatment of rabies and tetanus. All these antisera have in common one feature; they are polyclonal antisera, that is, the serum contains many different antibodies directed against the specific antigen which have been produced by many lymphocyte clones.

This polyclonal response is a characteristic of the normal immune response. Regardless of the size of the antigen, the antibody response consists not of one, but rather of many antibodies of different affinities, all of them directed against the antigen. These antisera are produced by injecting the antigen into an animal on repeated occasions and then harvesting the immune antiserum which can then be used for the purposes intended.

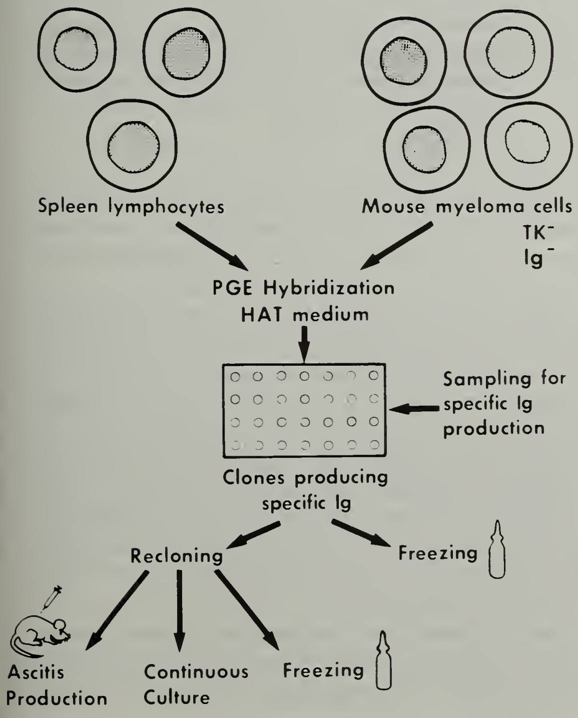
The weakness of this methodology rests on the variability of the immune response from individual to individual. It is not infrequent to find that one particular animal proves to be the best source for a particular antisera. Several animals injected with the same antigen may have antisera with totally different activities, making the production of continuously reliable antisera adifficult problem. Another obvious problem is the dependence on one particular animal or animals for the antisera. Production of new batches of antisera has to be started anew when those animals previously used are no longer available.

All these problems have been overcome through the

WILLIAM CIEPLINSKI, M.D., Assistant Professor of Medicine, Department of Medicine, University of Connecticut School of Medicine, Farmington, CT; Chief of Oncology, Hematology-Oncology Division, Newington Veterans Administration Medical Center, Newington, CT.

new monoclonal antibody technology. This technique takes advantage of cell fusion methodology for the production of stable hybrid lines that make one single specific antibody. The technology used is diagrammed in Figure 1. The breakthrough was achieved by Kohler and Milstein[1] who produced the first specific monoclonal antibodies. They postulated that immortality could be conferred on a normal antibody-producing B lymphocyte by fusing it with a malignant plasma cell mantained in long-term tissue culture in the laboratory. They hoped that the hybrid cell would keep both the ability to produce the specific antibody (derived from the normal B lymphocyte) and the ability to continue to reproduce in long term culture (derived from the malignant plasma cell line).

Kohler and Milstein fused cells obtained from the spleen of a mouse immunized with sheep red blood cells (sRBC) with cells from a mouse plasma cell line. They assumed that at least some of the B lymphocytes making anti-sRBC antibody would be located in the spleen. They needed a mechanism to eliminate both the unfused plasma cells as well as any self-self fusions occurring, so they used an elegant biochemical manipulation to induce an enzyme deficiency in the malignant fusion partner.[2,3] After the fusion, a selective culture medium was used that killed the cells with the enzyme deficiency but allowed the hybrids to survive, thanks to the enzyme contributed by the normal spleen cells. The normal B lymphocytes live only a short time in culture, so unfused cells die.



In this fashion, only true hybrids survived and the clones were then tested for their ability to produce anti-sRBC antibody. When the hybridoma clones began to grow, the supernatant culture medium was screened for the specific antibody activity. They found that 11% of the hybrids produced anti-sRBC antibodies. Each clone, being the product of the fusion of a single spleen cell with a single myeloma cell, produced only one antibody, hence the name monoclonal antibodies. Large quantities of each monoclonal antibody could then be obtained by allowing continuous growth of the hybridoma line and collecting and purifying the supernatant. Moreover, the clone could be frozen and thawed without loss of antibody secretion, and antibody production could be enhanced by one or two orders of magnitude by injection of the hybridoma cells into the peritoneal cavity of mice primed previously by the injection of the mineral oil pristane and purifying the antibody from the ascites thus produced.

This methodology therefore allows for the production of large quantities of single, highly specific antibodies. This high specificity allows the investigator to pinpoint very small antigenic differences that heterologous antisera fail to distinguish, because of the very nature of the multiple antibodies they contain. Table 1 shows a short list of the most important distinguishing features between polyclonal antisera and monoclonal antibodies. As can be seen, another advantage of the methodology resides on the ability to use partially purified antigens for the immunization. Because the selection of the appropiate clone is done after the fusion by looking for the specific activity desired, the clones with specificity for any of the contaminants can be safely eliminated.

Table 1
COMPARISON BETWEEN POLYCLONAL ANTISERA AND MONOCLONAL ANTIBODIES

Polyclonal Antisera	*Monoclonal Antibodies*
1. Mortal	Immortal (More or less)
2. Multiple Specificities	Unique Specificity
3. Difficult to reproduce from animal to animal	Stable in culture and recoverable from frozen storage
4. Purity of antigen almost indispensible	Antigens may be impure

Table 2 shows some of the clinical uses for which monoclonal antibodies have been employed. The identification of cells using immunochemical techniques has advanced markedly since monoclonals became available. Probably the best known application has been in the field of lymphocyte classification. The use of a number of commercially available panels of monoclonals has allowed the routine classification of lymphocytes into B and T types, and more importantly, to subclassify the T cells into the "Helper" and "Suppressor/Cytotoxic" subgroups. This work was pioneered by the group headed by Schlossman and Reinherz and is reviewed in reference 4. The availability of these monoclonals has allowed the gathering of large quantities of clinical information from a number of clinical disorders with an immune pathogenesis. A number of abnormalities of these subgroups and of the Helper/Suppressor ratio have been found in clinical conditions such as Systemic Lupus Erythematosus, patients with hemophilia, patients with the Acquired Immunodeficiency Syndrome (AIDS), to mention just a few.[5-8]

Table 2
APPLICATIONS OF MONOCLONAL ANTIBODIES

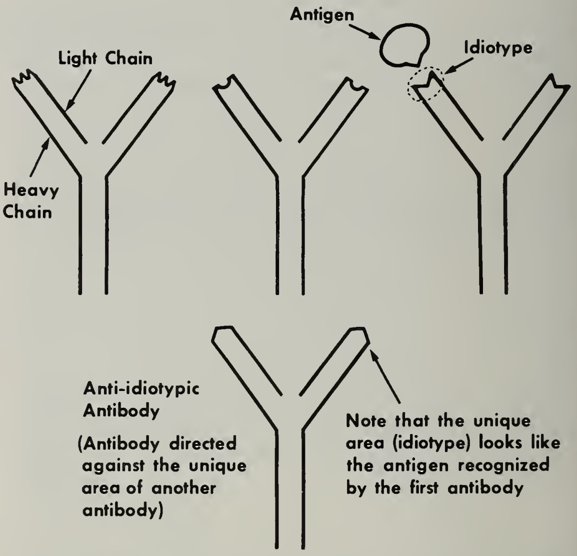
1. Identifying cells
    a) Lymphocytes, T & B
        Subclasses: Helper
        Suppressor
        CTL
    b) Stages of Differentiation
    c) Immuno-histo-chemical techniques
2. Diagnosis
    a) Imaging with radiochemicals
    b) Detection of circulating marker proteins like – fetoprotein, HCG and CEA
    c) Specific purification of enzymes typing of bacterial and viral organisms
3. "Magic Bullets" Cell Targeting
    a) Infusion of antibodies only
    b) Coupling to chemotherapy agents or toxins
4. Anti-idiotypic Monoclonal Antibodies
    a) Antitumor activity in B cell neoplasias
    b) As analogs of antigens for immunization and other applications

The monoclonal antibodies directed against the T cell subgroups have also been used in vivo for the monitoring and treatment of graft rejection after kidney transplantation. Russell et al[9] have studied the effects of monoclonals directed against Helper T cells as well as an antibody that recognizes all mature T cells in monkeys after renal transplantation. These same authors have used the anti T cell antibody successfully to treat rejection of the graft in human recipients.[10]

However, the clinical area where monoclonal antibody technology has generated the highest degree of excitment is in oncology. The concept of using serotherapy for the treatment of cancer goes back to Paul Ehrlich, the creator of the "Magic Bullet" concept, who in 1906 suggested the use of specific antisera that would home in on the malignant cells.[11] With the advent of the new technology, the possibilities for the production of specific antibodies capable of recognizing tumor-specific antigens became readily apparent. These antibodies would then be used for the specific diagnosis and treatment of malignant tumors. Many laboratories have tried to produce monoclonal antibodies directed against tumor-specific antigens by injecting tumor cells into mice and then fusing the spleens of the mice with myeloma lines in culture.[12-17] This specificity is intuitively very important, as the main goal is to obtain antibodies that will recognize and target the malignant cells while sparing the normal cells. Unfortunately, no such tumor-specific antigens have been found despite numerous attempts. Most antibodies initially thought to show tumor specificity, have been shown to be in fact directed against differentiation antigens. Consequently, a number of cross reactions with normal cells or with cells from apparently unrelated types of tumor cell lines have been encountered.[18-20]

One notable exception to the statement questioning the existence of tumor specific antigens is seen in the B cell lymphocyte neoplasms. These malignancies, consisting of the majority of patients with chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphomas (NHL), carry on the cell surface the unique immunoglobulin (Ig) that the single (cloned) B cell from which the neoplasm was derived, continues to produce. This Ig is unique in its F_{Ab} portion, the side that combines with antigens and is antigen-specific. This is the idiotype region (Id), and specific monoclonal anti-idiotypic antibodies (anti-Id) can and have been produced (Figure 2).

IDIOTYPE AND ANTI-IDIOTYPIC ANTIBODIES


Antigen
Idiotype
Light Chain
Heavy Chain
Anti-idiotypic Antibody
(Antibody directed against the unique area of another antibody)
Note that the unique area (idiotype) looks like the antigen recognized by the first antibody

Despite the lack of tumor specificity, a number of attempts have been made to treat malignant disease using some of these antibodies directed against differentiation antigens present on malignant cells as well as on some normal host cells. Bernstein et al,[21] described an animal model in which they used one such monoclonal antibody and were able to eliminate all the leukemic cells without damage to normal cells. Ritz et al,[22] used a monoclonal antibody directed against a differentiation antigen present during B cell development to treat acute lymphocytic leukemia in children. This antibody, J-5, is directed against the Common Acute Lymphocytic Leukemia Antigen (CALLA). They were able to reduce the number of leukemic cells in circulation by repeated injections of the mouse monoclonal.

There have been other attempts at in vivo treatment of human malignancies using monoclonal antibodies directed against differentiation antigens.[23-27] Some of these have concentrated on the T cell malignancies, particularly the cutaneous T cell leukemias. Miller and Levy[26-27] showed some partial remissions in patients with this type of malignancies with relatively minor toxicity. They noted that relapse was frequently associated with generation of host antibodies directed against the mouse monoclonal.

Other useful facts have been learned from these studies. In order for the antibody to be effective in eliminating tumor cells in vivo, it must have the Fc portion. The most important mechanism of tumor cell destruction in animal studies involves uptake of antibody coated cells in the reticuloendothelial (RE) system or through killing by phagocytic cells in the local area. Antibodies of the IgM class are far less effective in this system than those of the IgG class.

Ritz et al, in the study with J-5 antibody (Ab) described above noted a phenomenon called modulation of antigen (Ag). The leukemic CALLA + cells began to decrease their expression of the CALLA Ag after several exposures to the J-5 Ab. Tumor cells can escape the antibody effects by other mechanisms as well. These mechanisms include: a) antigenic heterogeneity, that is, some of the tumor cells may not express the particular antigen that the antibody is directed against, b) exhaustion of the effector system, either by the local macrophages or the RE system. However, other immune mechanisms may be operative and enhanced by antibody—i.e. ADCC (Antibody Dependent Cell Cytotoxicity), etc.

Anti-idiotypic antibodies have been used by R. Levy and his group at Stanford University to induce a complete response in a patient with a nodular lymphocytic poorly differentiated lymphoma (NLPD) that has continued, unmaintained, for over two years.[28] This is truly remarkable in view of the fact that the patient was resistant to multiple chemotherapeutic agents and had widely disseminated disease from which he would have died almost certainly within weeks to a few months.

Dr. Levy's group has treated several more patients using the same type of anti-idiotypic monoclonal antibodies, and while they have not been able to repeat the complete remission result they obtained with the initial patient, they have been able to produce several partial remissions.

At the same time, they have identified a number of pitfalls and problems to be confronted and surmounted. Among the problems encountered, the ones that stand out are the following: a) Idiotype-Antiidiotype interaction with complex formation in those patients who have a significant amount of the idiotype in circulation; b)generation of antimouse antibodies by the patient, inactivating the monoclonal antibody infused. They have also encountered modulation of the surface idiotype as well as instances of possible biclonality of the malignant population of cells.[29-33] There are attempts to overcome all of these problems by a number of techniques. One modality, increasingly mentioned in the literature consists of the coupling of the monoclonal antibody through a covalent linkage to either a chemotherapeutic drug or to a toxin. The hybrid molecule would home in on the malignant cells and deliver the chemotherapy, thus presumably decreasing or obviating the side effects that so frequently complicate regular chemotherapy regimes. There have been no reports in the literature yet about such an in vivo attempt, but there is in vitro evidence that this modality of treatment is feasible.[33].

Another modality of treatment receiving considerable interest involves the treatment of autologous bone marrow from patients with leukemia with monoclonal antibodies in vitro. This eliminates the leukemic cells present in the bone marrow extracted from the patient. The patient is then subjected to bone marrow ablation with radiation and chemotherapy and the in vitro treated bone marrow, now presumably free of leukemic cells, is then reinfused to the patient as an autologous bone marrow transplant to replace the leukemic marrow ablated. Preliminary results suggest that this may be a feasible form of treatment for some forms of acute leukemia.

One extremely interesting possible use of monoclonal antiidiotypic antibodies is in the area of vaccines and immunization. As mentioned previously, the idiotype region is the area of the antibody that recognizes the antigen. The antiidiotype recognizes the idiotype also; therefore it follows that some antiidiotypic antibodies may have a tertiary and quaternary structure similar to the antigenic site of the antigen (Figure 2). As such, an antiidiotypic antibody could be used instead of an antigen for vaccination and immunization. This would help decrease the reliance on attenuated virus vaccines that have side effects that may sometimes be quite serious.

In summary, the availability of monoclonal antibodies has opened new avenues for the study of a number of disease states. These antibodies may also have a place in the treatment of a number of diseases including transplantation rejection and some malignancies. They have offered new tools for the characterization of cell lines and tumors that go beyond simple morphologic description and give information also about degrees of differentiation. Finally, they may provide new tools for vaccination that may obviate the need for attenuation of viruses and perhaps decrease the reactions associated with these vaccines. These are but a few of the possibilities for clinical use for this exciting technology, less than 10 years old. I am sure that the future will amplify on the above and perhaps provide other possibilities not yet thought about.

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Quarantine and AIDS

ALVIN NOVICK, M.D.

ABSTRACT—Recent Connecticut legislation has authorized quarantine, under certain conditions, for persons having a communicable disease. In the event that this legislation comes to be applied to persons with AIDS, substantial organizational planning will be required. In addition to outlining some of those planning needs, the creation of a review board, advisory to the Commissioner of Health Services, is proposed.

In June 1984, legislation was enacted in Connecticut permitting the quarantine of persons with communicable diseases who are judged to be a threat to public health.[1] The pertinent wording is as follows: "Any town, city or borough director of health may order any person into confinement whom he has reasonable grounds to believe to be infected with any communicable disease . . . and who is unable or unwilling to conduct himself in such manner as to not expose other persons to danger of infection . . . whenever such director determines such person poses a substantial threat to the public health and such action is necessary to protect and preserve the public health." [Later] "A person confined under this section shall have the right to a court hearing . . . The hearing shall be held to determine if (1) the person ordered confined is infected with a communicable disease . . . , (2) the person poses a substantial threat to the public health, and (3) confinement of the person is necessary and the least restrictive alternative to protect and preserve the public health. The Commissioner of Health Services shall have the right to be made a party to the proceedings."

The extent to which this legislation is currently, or may come to be, applicable to persons with AIDS or related illnesses, or to those who are judged to be carrying or able to transmit the AIDS agent has not been established. If it is to be applied, procedures must be established that are so sensitive and rational that they can be understood by reasonable people to be necessary, appropriate, respectful of persons, beneficent, and fair.

We need a broad spectrum of analyses and plans to prepare for the possibility that this legislation will come to be applied to AIDS. In order to permit positions of support and opposition to develop, open discussions will be necessary. The public must expect responsiveness to serious concerns, and accountability, as well. In that there is no designated official authority who is empowered to establish procedures, we may expect that significant and sensitive planning, on the states's part, may be postponed. That burden, for now, may fall heavily or exclusively on patient advocates,[2] but they lack authority to establish policy and lack funding to do the necessary extensive planning.

Substantial planning commitment is also needed now to develop educational programs and counseling procedures and to foster research that may preclude the need to consider quarantine.

Specifically we may anticipate at least the following needs. Physicians, epidemiologists, ethicists, civil rights attorneys and, above all, patient advocates must be in a position to help assess the public health need and the quarantined person's rights and to help the involved public officials to evaluate the situation both scientifically and humanely.

Among those who may benefit from sensitive scientific, public health, and humane advice are the person who has been quarantined, his or her legal representative, the local director of health, the State Commissioner of Health Services, the judges of the Probate Court assembled to review the need for quarantine, those involved in enforcing the quarantine restrictions and the media.

Our knowledge of AIDS is advancing much more rapidly than is the available analytical medical literature. Many of the persons involved with application of the quarantine legislation will need detailed information on the nature of AIDS and related illnesses, the infectiousness of the AIDS agent, how, when, and by whom the agent can be

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ALVIN NOVICK, M.D., Professor of Biology, Yale University, Faculty of Arts and Sciences, New Haven, CT.

Reprint requests to: Department of Biology, Yale University, P.O. Box 6666, New Haven, CT 06511 (Dr. Novick).

transmitted, and risk reduction possibilities. They will also need to know with what degree of certainty one can make the given diagnosis, with what degree of certainty one can assess transmission potential, when and how one would subsequently ascertain that the transmission potential had ceased, and in what sense the person could medically be said to have a communicable disease that required isolation for the public good. Further advice would be needed on the degrees and sorts of isolation that might be required and which, in the most ethical and humane fashion, would be likely to balance the public's interest vs. the quarantined person's rights. Yet further advice would be needed on powerful and non-invasive alternatives to quarantine such as counseling and education.

Such a focused explication of what we know of AIDS and transmission of the AIDS agent, designed to elucidate these matters for lawyers, judges, and directors of health can be prepared now, *updated regularly,* and await the need. Without such documents, the procedures may well be chaotic and run the risk of unfair and inappropriate outcomes.

Careful analysis and planning is needed around the matter of how we will come to recognize potential candidates for isolation. The confidentiality of research data must be inviolate if we are to expect full cooperation from research subjects[3,4] and the confidentiality of medical records must also receive a high degree of respect.

Substantial analytical advice will also be needed on the social consequences of quarantine (for the individuals involved and for society), differentially developed for different scenarios. For example, quarantine might be imposed in the person's home, in a public or private chronic or acute care facility, or in a specialized institution designed for persons with AIDS. Some individuals may be subjected to scrutiny or to quarantine on the basis of tests showing them to be carriers of the AIDS agent or showing them to have antibody titers against the AIDS agent.[5] There are particularly difficult social and ethical concerns surrounding the development and application of these tests. Some of the persons, who test positive, would look and feel well and their future course of health cannot now be predicted. It would surely be inappropriate to confine them to a hospital, and the social consequences of restricting their freedom could well be devastating to them and to society.

The costs to the public of health care and general support for quarantined persons must be estimated. Access to full health care, for example, would have to be planned and quaranteed since these persons would have lost the means for financing their own care. How would the person's financial affairs be kept in order. How would his family's needs be met and his home and job preserved? How would he ultimately be restored to his place in society? How would adequate and fair counseling be assured to meet the patient's social needs and to help him to cooperate in adjusting to society's demands? Who is to help him understand his rights and defend them? Ultimately, I believe that patient advocates[2] must help to formulate these plans, help to assure their accessibility, and prevail on public agencies to bear some of the burden. We may anticipate that conflicts of interest will arise between the privacy of confined persons and the need for the public and patient advocates to know what is going on and how it is justified. Patient advocates must have reasonable access to confined persons and confined persons must have access to the potential advocates. The ethical conflicts must be analyzed and resolved in the most sensitive fashion.

The public should expect a person's civil and human rights to be no more violated than necessary to protect against a *factually based*and *substantial risk to the public health.* To help assure such balance, patient advocates must have access to the facts and the reasoning. I would anticipate great resistance, both bureaucratic and paternalistic, to allowing such access. Reasonable procedures should be worked out beforehand.

At present, quarantine appears likely to be prohibitively costly to the public, in setting the precedent of depriving persons of rights without substantial benefits, and very invasive and costly to confined persons. We may conjecture that it may sometimes come to be imposed as a political or social sanction against the vulnerable rather than for demonstrably valid public health reasons. We must demand that it be used only when truly necessary and appropriate and that the confined persons then be assured of maximum protection, compassionate health care, respect, and justice.

I believe that to facilitate orderly procedures we should move to establish a review board, in Connecticut, as an arm of the Commissioner of Health Services, composed of medical scientists, epidemiologists, public health administrators, patient advocates, ethicists, and civil rights attorneys. Such a publicly authorized and accountable board should be formally charged with overseeing the application of the quarantine legislation and with serving as an advisory council to local directors of health and to the State Commissioner of Health Services. We should expect this board to commission planning, to analyze and judge the fairness and balanced appropriateness of procedures, to review all acts of enforcement, to set standards for sensitive and humane care, and to seek funds to subsidize the necessary planning when outside agencies are involved. This board should have the status and power to win public confidence.

This review board should also identify important research needs, help in establishing substantial educational programs for the general public, for persons at-risk for AIDS or related illnesses, and for health care professionals, and help in establishing training programs for specialized AIDS risk-reduction counsellors. Such programs, while costly, will surely help to preclude the need to consider application of the quarantine legislation and its potential to harm both the isolated individuals and society.

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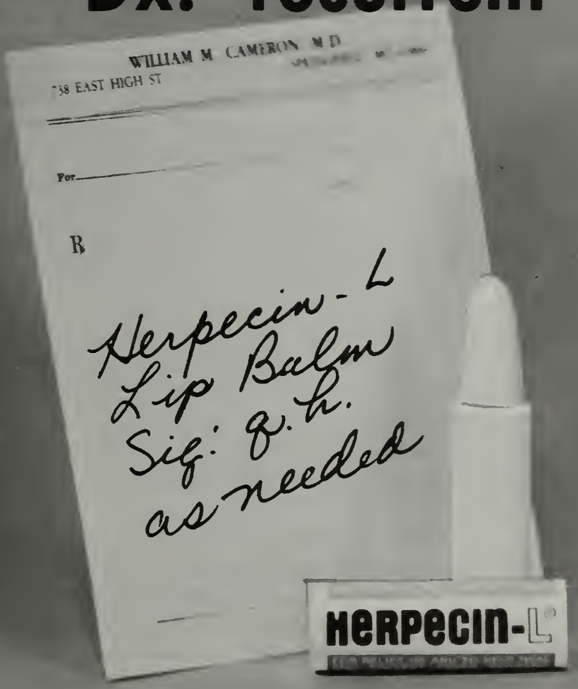

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Important Advances in Clinical Medicine

Epitomes of Progress—Allergy

The Scientific Board of the California Medical Association presents the following inventory of items of progress in allergy. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in allergy that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Allergy of the California Medical Association and the summaries were prepared under its direction.

Platelet-Activating Factor

The most recently recognized and possibly the most potent cell-derived mediator of inflammation and bronchoconstriction is platelet-activating factor (PAF). This name was derived in the early 1970s when it was learned that leukocytes from allergic rabbits exposed to a specific allergen produced a substance capable of aggregating and inducing secretory activity of platelets. Rabbit and human plasma and serum contain an enzyme (PAF acetylhydrolase) that rapidly destroys platelet-activating factor. Acidification of plasma to inactivate this enzyme has permitted the detection of PAF during anaphylaxis in rabbits and in association with urticaria in humans. The structure of PAF was discovered almost simultaneously by three independent laboratories in 1979. It is a novel ether phospholipid mediator with the structure 1-alkyl-2-acetyl-*sn*-glyceryl-3-phosphorylcholine known as AGEPC or PAF-acether.

PAF is not preformed or stored in cellular granules, as is the case with histamine. Instead, it is newly synthesized following the appropriate stimulation of a variety of cells. Human cells known to produce PAF are neutrophils, eosinophils, monocytes, macrophages, alveolar macrophages, endothelial cells, platelets themselves and possibly basophils and mast cells. Although named PAF because of its effects on platelets, this mediator elicits many other important inflammatory and physiologic events: polymorphonuclear leukocyte aggregation, chemotaxis and enzyme secretion, stimulation of monocytes, hypotension, contraction of bronchial and visceral smooth muscle and increased vascular permeability. Many of these activities are independent of platelet activities. Injecting PAF into human skin induces immediate skin blanching indicative of acute vasoconstriction, which is often associated with burning pain and pruritus. An intense histamine-like wheal and flare reaction then develops, reaching a maximum intensity after 10 minutes and subsiding within 60 minutes after administration. PAF-induced vasoactive effects occurred at concentrations at least 1,000 times less than was required for histamine. PAF is 600 times more potent than leukotriene D_4 (or slow-reacting substance of anaphylaxis) and 20,000 times more potent than histamine in causing airway reactivity in rhesus monkeys.

The exact role of PAF in human disease remains to be proved and clarified. However, very recently it has been learned that PAF is released into the venous blood of patients with acquired cold urticaria when their arms are immersed in ice water. This is the first demonstration that PAF is released during a human disease event but there is still no proof of a causal relationship between the release of PAF and the urticaria.

In summary, PAF has proved to be an extremely potent mediator of a variety of physiologic and inflammatory events in animals, subhuman primates and humans. It is the subject of a great deal of current investigation that includes its possible role in human disease and a search for molecules that will either block the effects of PAF on target cells or prevent its release after a variety of stimuli.

Richard S. Farr, M.D.
Denver

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Long-Acting Theophyllines

Long-acting theophylline preparations, designed for once-a-day dosing in relatively healthy adults who have asthma, have become available for prescription usage in the United States within the past year. These sustained-release medications provide stable therapeutic blood concentrations, effective bronchodilation and bioavailability similar to the twice-a-day theophylline preparations with, for some patients, the added convenience of once-a-day administration. Long-acting theophyllines can usually be given in one daily dose equal in milligrams to the daily dose of a shorter-acting theophylline preparation. Although the primary toxicities of the long-acting theophyllines are those from theophylline in general, so that precautions in methylxanthine administration apply to all types of theophylline preparations, additional precautions pertain to long-acting, once-a-day theophylline preparations.

Smokers metabolize theophylline very quickly and often require twice-a-day administration of the “24-hour” preparations. The elderly, those with congestive heart failure and those who have hepatic dysfunction are at an increased risk for toxic effects due to slow theophylline metabolism and therapy should be started at low doses and their blood concentrations monitored carefully. Manufacturers recommend that a single dose of sustained-release theophylline be given in the morning due to variations in drug levels with posture, activity and food intake. Because very large doses of some theophyllines taken with meals may result in erratic gastrointestinal absorption and unpredictable theophylline blood concentrations, taking the daily dose on awakening—one to two hours before breakfast—may eliminate this potential problem. Twice-a-day preparations may provide more stable blood theophylline concentrations in some patients requiring large theophylline doses.

When acute bronchospasm necessitates urgent theophylline therapy, an immediate-acting theophylline preparation or intravenous administration of aminophylline (theophylline with ethylenediamine) is indicated. Long-acting theophylline preparations should be reserved for long-term theophylline maintenance therapy particularly when improved patient compliance and convenience are of concern. They are well tolerated and may be used safely by monitoring serum theophylline concentrations and clinical responses.

Diana L. Marquardt, M.D.
San Diego

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Neutrophil Chemoattractant Receptors and Inflammation

The importance of neutrophils (polymorphonuclear leukocytes) in the inflammatory process has been appreciated for more than a century, and yet the mechanisms by which they are able to carry out directional locomotion into sites of tissue inflammation is poorly understood. In the past seven to eight years a great deal of knowledge has been accumulated that indicates that the locomotory or chemotactic ability—as it is most often referred to—of nuetrophils is due to the presence of specific cell surface receptors for chemoattractants, that is, chemical towards which the cells move in a directed manner. There is good evidence that many of the functions that the neutrophils carry out as part of their inflammatory activities—such as migrating into the tissues, engulfing foreign bodies, increasing oxygen metabolism and production of toxic oxygen species and microbial killing—are initiated through receptor-mediated cell activation.

A number of chemoattractant receptor systems have been described on the surface of neutrophils, each of which appears to be separate and non-crossreacting and yet all lead to common pathways of cell activation and must therefore be linked at some postreceptor point.

Receptors for fragments of the fifth component of complement ($C5_{Fr}$) are considered extremely important in directing neutrophils into areas of inflammation where complement activation is felt to be an important aspect of the disease pathophysiology, such as serum sickness, immune vasculitis and cryoglobulinemia. There is also very good evidence that complement receptor-induced neutrophil activation and subsequent pulmonary leukostasis are important in acute lung injuries (shock lung syndrome) associated with trauma or sepsis.

The most extensively studied chemoattractant system is that for synthetic *N*-formylated peptides that are felt to be identical or closely related to naturally occurring bacterial products and thus are important as a model of neutrophilic response to infection. Studies of the formyl peptide receptor system have shown that certain anti-inflammatory agents (especially glucocorticoids) may affect neutrophil function through interactions at the receptor level in addition to their numerous other biologic actions.

Another chemoattractant receptor has been described for a chemotactic factor produced by neutrophils themselves after ingestion of sodium urate or calcium pyrophosphate crystals. Neutrophil activation by this receptor has been postulated to be an important amplification system contributing to the acute inflammation often seen with crystal-induced arthritis.

Most recently, there has been great interest in the role in inflammatory reactions of lipid molecules generated from arachidonic acid, especially the hydroperoxy and hydroxy fatty acids (HPETEs and HETEs) and leukotrienes produced through the action of a lipoxygenase enzyme. In neutrophils, hydroperoxyeicosatetraneoic acids (HPETEs) are further metabolized to a group of compounds termed leukotrienes. The leukotrienes possess potent inflammatory activities and include the sulfidal peptide constituents of slow-reacting substances (C_4, D_4 and E_4) and the dihydroxy leukotriene B_4. Goldman and Goetzl have recently shown a distinct and specific receptor for leukotriene B_4 on neutrophils, and they and others have elucidated the functional responses of neutrophils to leukotriene B_4. Although much is still unknown regarding the role of the leukotrienes in inflammation, their potency and ubiquity make them strong candidates as inflammatory mediators or modulators in many disease processes involving recruitment of inflammatory cells. Present efforts are being directed toward the development of specific inhibitors of leukotriene formation. Such agents would be very useful for basic research on the interaction of arachidonic acid metabolites and of great therapeutic potential in the treatment of asthma, rheumatoid arthritis or other related conditions.

Elucidation of increasing numbers of surface receptors for diverse chemoattractants on neutrophils, together with the understanding that the various neutrophil functions are triggered by occupation of these receptors, provides basic information for a clearer understanding of neutrophil function in inflammatory conditions and will likely provide clinicians with more disease-specific and effective therapies in the near future.

Mark P. Fletcher, M.D.
Davis, California

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Clinical Significance of Helper/Suppressor T Cells

The morphological determination (typing) of the percent and absolute number of circulating T-"helper" and -"suppressor" lymphocytes has gained widespread popularity with the development of monoclonal antibodies to detect antigens on the surface of different subpopulations of human lymphocytes. In this context, the terms T "helper" and "suppressor," which are functional terms, are gross oversimplifications. The helper T cells, as detected by the monoclonal antibodies in general use such as T4, contain not only helper cells for immunoglobulin synthesis but also inducer cells for many T-cell functions and even the precursors of some suppressor T cells. Thus, the T-helper/inducer population is really a mixture of related but distinct T cells. These distinctions based on function can be delineated immunologically by other monoclonal antibodies not in general use. Similarly, the suppressor T cells defined by monoclonal antibodies such as T8 comprise a variety of cell types involved in cytotoxicity and in inhibition of immune responses.

The measurement of helper and suppressor T-cell numbers, percents and ratios can be compared with the measurement of different types of leukocytes by differential cell count. Values may be abnormal in many cases but the clinical utility is limited to a very small number of disorders. Furthermore, while the test is very sensitive, it is also nonspecific, being altered in many infectious (especially viral), metabolic, neoplastic, rheumatologic and congenital and acquired immunologic disorders. Quantitation of helper/suppressor T cells may be clinically useful in certain suspected immunologic disorders. In infants, it can be used to distinguish between transient hypogammaglobulinemia (reduced helper T cells) and congenital agammaglobulinemia (normal helper/suppressor T cells and absent B cells). In adults, T-cell subsets are most often measured in the evaluation of persons suspected of having the acquired immune deficiency syndrome (AIDS). While a reduced number (and percent) of helper T cells with a normal or increased percent of suppressor cells is almost uniformly found in patients who have AIDS, these findings are very nonspecific and, in themselves, not diagnostic. Moreover, altered helper/suppressor T-cell ratios are found after a viral infection and in many sexually active homosexual men who do not have AIDS. Thus, while an abnormal helper/suppressor T-cell ratio is a characteristic immunologic finding useful in confirming the diagnosis of AIDS, it is by no means diagnostic of the disorder. In other adult immunodeficiencies, such as common variable immunodeficiency, T-cell subsets (by the generally used markers) are often abnormal but appear to have no relationship to the in vivo or in vitro functional defects observed.

Measurement of helper/suppressor T cells is not a screening test. In selected patients with possibly abnormal T-cell function, it should be used in conjunction with other tests of immune function such as a battery of delayed hypersensitivity skin tests. It is important to emphasize that patients should not be labelled as having an "immune disorder" or "dysfunction" solely on the basis of an in vitro morphologic determination of helper/suppressor T cells.

Andrew Saxon, M.D.
Los Angeles

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Penicillin-Induced Anaphylaxis

Of an estimated 400 to 800 anaphylactic deaths per year in the United States, as many as 75% have been ascribed to penicillin sensitivity. Anaphylaxis may occur in one to four instances per 10,000 patient treatment courses. The death rate is about 1 to 2 per 100,000 patients treated. The oral route appears to be the safest but reactions and even death have occurred from penicillin taken orally. Children are at lower risk than adults.

Penicillin is the only drug whose allergenic metabolites have been identified. The penicilloyl moiety, formed in largest quantity and thus called the major determinant, is responsible most often for accelerated urticarial reactions. A skin test reagent for detecting sensitivity to this determinant is available commercially as penicilloyl-polylysine. Some ten other antigens comprise the minor determinants but test reagents for these are not available for routine use. IgE antibodies to penicilloate and other minor determinants are associated with anaphylactic sensitivity. Preformed conjugates and self-polymers that may be present in penicillin preparations are thought by some investigators to play a role in penicillin anaphylaxis.

The presence of penicillin-specific IgE is conveniently and rapidly shown by immediate wheal and erythema skin testing. Although sometimes a screening procedure, penicillin skin tests are usually done in patients who require penicillin for a serious infection and who have a history of penicillin allergy. Prick followed by intradermal tests is done with penicilloyl-polylysine, various concentrations of the aqueous fresh penicillin to be used and proper controls. Significant reactions to subsequently administered penicillin are unlikely in skin test-negative patients. Persons without a history of penicillin allergy have a 7% or less incidence of positive skin tests. Clinical histories suggestive of IgE-mediated reactions yield a 17% to 46% positive skin test rate, depending on the type of previous reaction and the time elapsed between the reaction and skin testing.

Past sensitivity wanes with time and future sensitization may occur anytime. Consequently, skin testing is relevant only to a current clinical situation. It is safe when properly done. In vitro testing for specific IgE to penicilloyl by radioallergosorbent test is promising because it would avoid the rate instance of reaction to skin testing, but it does not predict anaphylaxis.

In cases in which penicillin is still considered the drug of choice in the face of a positive skin test, desensitization may be done. Oral as well as parenteral methods have been proposed. Parenterally given desensitization is effective but cumbersome and can be associated with severe life-threatening reactions. Oral desensitization appears to be effective and relatively safe. It is usually accomplished with less severe reactions.

Elliott H. Brunner, M.D.
Zack H. Haddad, M.D.
Los Angeles

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Diseases of Cilia

The significance of ciliated epithelium in both health and disease of the human respiratory tract has been increasingly appreciated. Mucociliary clearance, a process highly dependent on the coordinated metachronal movement of cilia, is an important mechanism for protecting the upper and lower airways. Both primary and secondary types of ciliary dysfunction have now been described.

A primary defect in the ultrastructure of cilia, normally represented as nine pairs of peripheral microtubules around two central ones, appears to be important in the pathogenesis of the immotile cilia syndrome, a hereditary disease clinically characterized by bronchiectasis, sinusitis and situs inversus in half the cases (termed Kartagener's syndrome when the latter is present). Cilia in this disorder have congenital abnormalities in the microtubular apparatus necessary for normal ciliary beating. The most common specific defect seen on electron microscopy is absence of the dynein arms—structures that facilitate intermicrotubular attachment and reattachment, resulting in bending of the cilium. Other ultrastructural variations include absence of the radial spokes and transposition of the microtubules. The diagnosis is usually made in adults with a history of chronic pulmonary or sinus disease (or both); some men present with infertility due to immotile sperm. Ultrastructural defects of cilia are also found in children who have not only the expected sinopulmonary problems, but also chronic otitis or a history of neonatal respiratory distress syndrome. One case of a different type of a primary ciliary abnormality, the isolated absence of nasal cilia, has been described. The affected boy had problems with persistent rhinitis and either chronic sinusitis or undeveloped sinuses.

Secondary or acquired disorders of cilia can occur due to various external influences inducing changes in ciliated respiratory epithelium. Ciliary dropout and damaged cilia along with decreased mucociliary clearance have been seen in patients who have allergic rhinitis after local nasal antigen challenge. Similarly, tracheal mucous transport rates, as measured by a technique using labelled Teflon particles, are diminished in patients with asthma, and antigen challenge causes further impairment. This dysfunction may be due to a ciliary inhibitory factor in sputum, possibly a leukotriene, though mucous changes are more likely to be the determining factor in asthma. Long-term cigarette smoking can lead to ciliary changes including swollen, compound cilia and even cilia with "9 plus 2" ultrastructural aberrations. Short-term cigarette smoke exposure can either diminish or enhance mucociliary clearance, the latter probably due to direct parasympathetic stimulation by nicotine. Chronic sulfur dioxide exposure, topical nasal decongestant use, aspirin administration and *Mycoplasma* infection have all been associated in humans or animals with either cilia detachment or decreased mucociliary activify, or both, thereby possibly compromising nasal and lung defense mechanisms.

Michael J. Welch, M.D.
San Diego

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Topically Applied Corticosteroids and Cromolyn Sodium in Managing Rhinitis

Corticosteroids are effective in treating various forms of rhinitis. The usefulness, however, of this class of drugs has been severely hampered by the profound side effects occurring as a function of time, dosage and individual sensitivity. In an effort to circumvent this problem, efforts have been directed toward the development of topically applied glucocorticoids capable of effecting a high degree of potency while being absorbed in insufficient amounts to cause adrenal suppression or cellular toxicity.

Three topical corticosteroids have been approved in the United States for the treatment of rhinitis and a fourth is currently undergoing clinical trials. Dexamethasone phosphate (Decadron Turbinaire) induces some adrenal suppression at a dose of 1 mg per day (12 inhalations), thereby limiting its usefulness. Beclomethasone dipropionate (Vancenase or Beconase) has the advantage of slow absorption from mucous membranes and rapid metabolism, lending a significant degree of freedom from adrenal suppression at its therapeutic dosage range of 400 to 600 μg per day (8 to 12 inhalations). Flunisolide (Nasalide), like beclomethasone, is free of significant adrenal suppression at therapeutic dosages (200 to 300 μg or 8 to 12 inhalations per day) due to its "first pass" mechanism of elimination and a short half-life of 1.8 hours. Recent clinical trials with fluocortin butyl have shown similar efficacy and safety data.

Cromolyn sodium is a mast cell stabilizer that has proved relatively efficacious and very safe in the treatment of allergic bronchial asthma. It has recently been marketed as an intranasally given solution (Nasalcrom) for the treatment of allergic rhinitis. Clinical trials have indicated that it is probably as effective as antihistamine. Its usefulness is limited by frequent applications (four to six times per day). Furthermore, both cromolyn sodium and the topical corticosteroids do not usually produce an immediate response. This is important to emphasize when prescribing the medication because patients will expect a "nasal spray" to produce immediate dramatic improvement; similarly, usage "as needed" should be discouraged in favor of a regular regimen.

The choice of medication should be predicated in part on the severity of the disease, the presence or absence of polyps and the patient's prior response to medication. For example, Nasalcrom might be an effective medication in a patient who had excellent response to antihistamines but could not tolerate the drowsiness. On the other hand, if antihistamines are clearly ineffective or nasal polyps exist then a topical steroid such as beclomethasone or flunisolide should be considered.

Gary A. Incaudo, M.D.
Chico, California

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Rhinometry

Normal inspiratory currents first enter the nasal alae, then turn upward through the nasal valve and pass across the inferior and middle turbinates into the nasal pharynx. Fully 60% of an inspired breath, about 300 ml (presuming a tidal volume of 500 ml), is inhaled 16 to 20 times per minute; cold, dry air is warmed to about 30 °C (86 °F), moistened to 80% humidity and filtered. Under normal conditions and quiet breathing, there is an alternating cyclic activity within the two nares. A normal healthy person inhales the vast majority of inspired air through one nostril, due to the erectile tissue causing shrinking of the nasal turbinates on one side while the opposite turbinates are filling and thus partially occluding the other nostril. Deflections of the septum, masses in the nose or hypertrophy of the mucous membrane will obstruct the air flow. When partial bilateral obstruction occurs, the patient may perceive this as fluctuating unilateral obstruction.

Rhinometry is the measurement of nasal air flow. Air flow rate (V) is determined by the patency of the passage, the manner in which the air flows (laminar or turbulent) and the pressure difference (ΔP) from the external atmospheric pressure to the retronasal space.

Many methods have been used to measure nasal patency. Any acceptable technique requires the continuous measurement of V and ΔP. One currently popular technique is anterior rhinometry, so called because all measurements are obtained from the external surface of the nose. A pneumotachometer calibrated for flow rate is fitted with a plastic rubber-tipped nosepiece. This is placed against the opening of one nostril. As the patient inspires, air moves through the pneumotachometer. A pressure tap on the pneumotachometer measures external nares pressure. Another similar nosepiece is placed against the opposite nostril. This one is connected to a pressure transducer that records the pressure within the nostril reflective of the retronasal pressure. The signal from it is viewed on an oscilloscope, an XY recorder or a direct digital readout instrument. When a satisfactory recording has been obtained, the tubes are switched to measure the other nostril. Anterior rhinometry has the advantages of being simple to do (even small children may be easily measured), rapid (takes less than 30 seconds) and informative about the patency of each nostril. Furthermore, the values are readily reproducible when done by an experienced technician.

A second method is posterior rhinometry. It requires the retronasal pressure to be measured from a tube in the mouth. This technique usually uses a face mask fitted with a pneumotachometer. Generally, posterior rhinometry is more expensive and complicated. While some patients can do the maneuver immediately, others have to be trained to relax their tongue to allow the oral cavity to communicate with the retronasal space. Also, the mask technique provides only a total reading of air flow for the two nasal passages.

Another technique to measure nasal patency uses the Wright peak flow meter. This system evaluates nasal function during expiration, which seems less logical than inspiratory studies because patients complain of inspiratory difficulties when congested. In addition, the important nasal functions of air conditioning, cleaning and olfaction are carried out during inspiration. It should be noted that inspiratory flow values differ from expiratory because of the negative airway pressure and the flaring of turbinates into the airstream during inspiration. The least desirable aspect of this technique is that forceful expiration blows secretions into the measuring instrument.

Rhinometry can be valuable in medical practice. Clinically, the technique is useful in documenting and monitoring the degree of nasal obstruction. In diagnostic work it can help differentiate impairment due to structural or mucosal changes by obtaining values before and after a nasal decongestant; similarly, challenge studies can confirm the etiologic role of various inhalants. It may also be helpful in determining the effectiveness of medication or surgical treatment.

Eli O. Meltzer, M.D.
San Diego

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The Radioallergosorbent Test

The diagnosis and management of atopic allergic disease depends on correlating historical and physical findings with identification of IgE antibodies specifically directed at one or more allergens. Knowledge of specific antigen sensitivity is important in directing environmental controls, in predicting exacerbations (after exposure to pertinent antigens) and in planning appropriate immunotherapy when indicated. The radioallergosorbent test, or RAST, is the most commonly used in vitro assay for detecting these antibodies.

RAST is a sandwich-type radioimmunoassay. Allergen-specific IgE in a serum sample binds solid-phase coupled allergen usually on a paper disk. An anti-IgE antiserum will "sandwich" the bound IgE. After washing, the amount of radioactivity is proportional to the amount of specific IgE in the serum sample. Results are expressed semiquantitatively and are assigned to classes based on comparison with reference sera.

For clinical use, skin testing is generally considered more sensitive than RAST. Attempts to increase RAST sensitivity by lowering thresholds or by modifying the scoring system have generally led to an unacceptable number of false-positive results. RAST is, however, preferable to skin testing in selected instances. Patients with a history of anaphylaxis, especially some with pronounced food sensitivities, are at risk for exacerbation with skin testing, whereas those with severe dermatoses may present insufficient normal skin to permit accurate testing. Dermatographic patients may wheal and flare on a non–IgE mediated basis making skin testing uninterpretable. It is generally agreed that skin testing is contraindicated during pregnancy and that RAST is an acceptable alternative. Infants and toddlers with atopic disease are physiologically capabie of immediate hypersensitivity responses on skin testing and can be tested reliably. However, some children are made so anxious by procedures, even the minimally painful prick-puncture test, that RAST may be better tolerated. RAST carries no patient risk and may be performed in patients on antihistamines.

The radioallergosorbent test methodology has been useful in identifying the immune consequences of immunotherapy and for isolating and identifying allergenic components. Fractionated antigens can be assayed in RAST inhibition assays, in which soluble antigen competes with solid-phase antigen for antigen-reactive IgE. This method has also been successful in precisely quantitating potency of allergenic extracts, the more allergenic in the extract the greater the inhibition of the RAST. Such identification and quantification are crucial for the development of standardized allergen extracts. Establishing dose requirements for immunotherapy by RAST is currently under study, but present practice generally uses skin testing with pertinent antigens before instituting this therapeutic modality.

Skin testing has historically been less expensive, more flexible and more available than RAST. A number of commercially available technological variations of RAST now exist. However, the American Academy of Allergy and Immunology has warned of the potential for abuse in the form of questionable marketing tactics and poor quality control, which could lead to unnecessary testing and increased medical costs.

Despite the availability of new in vitro systems, skin testing is still less expensive and more sensitive and remains the standard for allergen-specific IgE detection; RAST must be regarded as a supplemental technique. Either method requires that a physician be trained in the use and the interpretation of these tests. The detection of allergen-specific IgE is only meaningful when it correlates with a patient's illness.

Seth Asser, M.D.
Robert N. Hamburger, M.D.
La Jolla, California

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Venom Immunotherapy in Children

The development of purified Hymenoptera venoms for the diagnosis and treatment of venom hypersensitivity has been a major advance in the care of allergic patients. To date, most information regarding this potentially lethal disorder (50 to 200 persons die each year in the United States) has been gathered in adults. Skin tests or a radioallergosorbent test, supplemented by a questionnaire, in adults has shown at 4% of the population has a history of sting reaction, and 20% has evidence of venom-related IgE antibody. Patients with positive skin tests and no history of prior reaction have about a 5% reaction rate to subsequent sting, and those with a history and a positive skin test about a 60% reaction rate. Thus, in adults there is a high incidence of sensitization and a predictable maintenance of responsiveness justifying venom immunotherapy for systemic reactivity.

Similar studies have yet to be fully carried out in children. One prospective analysis of children with mild systemic reactions (urticaria) has found, however, that venom reactivity in children is less fixed than in adults. Thus, instead of a 60% re-reaction rate, a systemic response developed to a second sting in only 10% of children who had a known prior Hymenoptera reaction. Moreover, none of the subsequent reactions were more severe than the initial one. In venom-treated children, the re-reaction rate is less than 10% and the severity of reactions is greatly diminished. Of particular diagnostic difficulty are reactions that ensue after stings in the face and neck, which cause larger local reactions and rapid absorption of venom with the potential for severe but possibly non-IgE-medicated reactions.

At present it is prudent to institute venom immunotherapy for skin test-positive children who have severe systemic reactions to Hymenoptera venom and in those few children whose mild systemic reactions are increasing in severity. The duration of such therapy is currently under study but present practice is to prescribe long-term, potentially lifelong, treatment. For those children manifesting a single mild reaction or repeated but stable or diminishing mild reactions, a watch-and-wait attitude (supplemented by providing an anaphylaxis treatment kit and education in its proper use) has been supported.

Stephen I. Wasserman, M.D.
San Diego

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Eosinophils

The eosinophil is a bone marrow-derived polymorphonuclear leukocyte found in blood (normal level, less than 300 per μl) and tissues in increased numbers primarily in allergic and parasitic disorders. The eosinophilia associated with immune events is T-lymphocyte-dependent and due to bone marrow stimulation by a specific eosinopoietic factor. Localization of the eosinophil to particular target organs is mediated by a variety of factors that selectively chemoattract the eosinophil. These factors include mast cell granule constituents, lymphokines, complement fragments, products of arachidonic acid metabolism (leukotriene B_4, hydroxyeicosatetraenoate [HETE]) and platelet-activating factor (PAF). The unique functions of the eosinophil are a consequence of its special constituents. These include major basic protein (MBP), a 10,000-dalton peptide that comprises 25% of the total granule protein, another cationic peptide (ECP) of 20,000 daltons, a special peroxidase, a neurotoxin and a 17,000-dalton lysophospholipase that can crystallize to form Charcot–Leyden crystals. This latter enzyme and MBP are also found in human basophils.

Eosinophil functions are both homeostatic and inflammatory. In helminth infestations, eosinophils can kill parasite larvae by MBP/ECP and peroxidase-mediated reactions, hasten expulsion of adult worms from the gut and enhance secondary immunity. In allergic reactions, eosinophils are capable of degrading histamine, leukotrienes and ether lipids such as platelet-activating factor, binding heparin and ingesting mast cell granules. Exuberant eosinophil reactions release MBP and induce eosinophil production of PAF and leukotriene C_4. The latter two are potent vasoactive-spasmogenic mediators, whereas MBP can degranulate mast cells and also kill ciliated cells and thereby produce histologic features in the bronchus similar to those seen in cases of asthma.

The ability of glucocorticoids to reduce eosinophil levels may thus underlie some of their clinical efficacy in diseases such as asthma. The development of agent(s) selectively active on eosinophils or on the unique eosinophil functions and constituents should provide another avenue of therapy for diseases such as asthma in which this cell is prominent.

Stephen I. Wasserman, M.D.
San Diego

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Immunologic Aspects of Cystic Fibrosis

Cystic fibrosis is a common heritable disease often manifested by cough and wheeze and complicated by a high prevalence of nasal polyps (6% to 24%), which occur at an early age. For these reasons, cystic fibrosis is occasionally confused with respiratory allergy, particularly early in life. A sweat chloride test is always indicated in children with nasal polyps and should be considered in the initial evaluation of very young children who have respiratory signs and symptoms.

Chronic cough, wheezing and hyperirritable airways are common features of both cystic fibrosis and asthma. The two diseases may coexist. Indeed, there is an increased prevalence of atopy in patients who have cystic fibrosis, and the possibility exists that cystic fibrosis predisposes to clinical allergic disease. Certainly the clincial manifestations of allergic respiratory disease are of a more troublesome nature in the presence of cystic fibrosis. Physicians who care for patients with either disease must be constantly alert to the possible presence of the other.

In cases of cystic fibrosis, recurrent and chronic respiratory infections are major problems, particularly those due to *Staphylococcus aureus* and *Pseudomonas aeruginosa.* In advanced disease, more than 80% of patients harbor *Pseudomonas.* It is of interest that atopic patients with cystic fibrosis are more likely to have persistent colonization with *Pseudomonas* than are nonatopic patients with cystic fibrosis.

Colonization by *Aspergillus* species is also common in cases of cystic fibrosis. In the presence of asthma and cystic fibrosis, it is difficult to make a diagnosis of allergic bronchopulmonary aspergillosis because of overlap in clinical and laboratory features. Studies suggest a 5% to 20% incidence of allergic bronchopulmonary aspergillosis in patients who have cystic fibrosis. Positive sputum cultures, eosinophilia, precipitins to *Aspergillus fumigatus,* immediate or dual skin test reactivity, elevated total serum IgE levels and IgG antibodies to *Aspergillus* antigens are useful screening tests for allergic bronchopulmonary aspergillosis in patients with cystic fibrosis. Aspergillosis should be considered whenever significant pulmonary manifestations of cystic fibrosis do not respond to antimicrobial therapy. Clinical improvement and improved pulmonary function following corticosteroid administration may suggest the diagnosis of allergic bronchopulmonary aspergillosis.

Some but not all investigators have reported depressed leukocyte locomotion in cases of cystic fibrosis. Circulating immune complexes were also found to be increased in this disease, particularly during acute infections. The relevance of these findings to the pathogenesis and course of cystic fibrosis remains to be defined.

It is important for all physicians to recognize the immunologic aspects of cystic fibrosis, the similarity of its early manifestations to atopy, the frequent coexistence of atopy and cystic fibrosis and the possible enhancing effect of atopy to fungal growth. Increased understanding of immunologic mechanisms in cystic fibrosis may lead to improved patient management in the future.

Eui J. Lee, M.D.
Douglas C. Heiner, M.D. Ph.D.
Torrance, California

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β-Adrenergic Agonists 1984

In the past decade several new drugs have been developed and marketed for the treatment of bronchial asthma that have improved β_2-specificity (bronchodilation greater than cardiac stimulation), that can be given by several routes of administration (oral, inhalation and parenteral) and that have a more prolonged duration of action (four to six hours) than epinephrine and isoproterenol. These improvements have come about by altering the basic catecholamine molecule. Changing the catechol nucleus to a resorcinol, such as metaproterenol sulfate or terbutaline sulfate, or salicyl alcohol (albuterol) decreases the agonists' susceptibility to enzymatic degradation resulting in more prolonged action and effective oral absorption. Increasing the size of the amino side chain substituent increases β_2-selectivity. β_2-Agonists are thought to have several actions in addition to bronchodilation, which make them useful in asthma, including inhibition of lung mast cell degranulation, increased mucociliary clearance and decreasing fatigability of diaphragmatic muscle.

Several recent studies have compared β-adrenergic drugs with theophylline for both acute and recurrent asthma. β-Agonists are superior to theophylline in alleviating acute asthma, whereas they compare favorably in controlling asthmatic symptoms over a several-week trial. In addition, when given simultaneously the effect of these drugs may be additive. Corticosteroids appear to restore β-agonist responsiveness in those who have become refractory, possibly by an increase in the rate of β-receptor synthesis.

In the oral form the newer β_2 drugs are more potent, selective and longer acting than ephedrine, which currently has little place in asthma therapy. Terbutaline (5 mg), fenoterol (5 mg) and albuterol (4 mg) are all comparable bronchodilators and more potent and selective than metaproterenol (20 mg). Although the efficacy of these agents has been shown in children 6 to 14 years of age, only metaproterenol is currently approved by the Food and Drug Administration for this age group. Epinephrine remains the most commonly used injectable sympathomimetic whereas terbutaline is also effective subcutaneously. Although theoretically advantageous, particularly in those with cardiac disease, terbutaline has not proved superior in children with acute asthma. Isoproterenol given intravenously is a useful treatment in children with respiratory failure and has not yet been replaced by the newer β_2-agonists.

The aerosol route of administration provides the greatest selectivity and effectiveness for β_2-agonists. Thus aerosolized metaproterenol from a metered-dose inhaler produces greater bronchodilation than the orally given form, though the dosage is only 10% to 20% of the oral dose. The onset of action and peak response are more rapid than with the oral form and side effects are less common, possibly because less drug is needed. The aerosol is also superior to the orally given form for exercise-induced asthma. Aerosols can be delivered by metered-dose inhaler of compressed-air jet nebulizer. Recently, auxiliary delivery systems using the metered-dose inhaler with spacers or reservoirs have been developed and show promise particularly in younger patients. Metaproterenol, terbutaline and albuterol are available in the metered-dose inhaler form, while metaproterenol solution is available for the jet nebulizer and can be used at home.

The most common side effects for the β_2-agonists are tremor and tachycardia. Because tolerance to these phenomena may occur after several weeks, one can begin with a reduced dose and gradually increase to the recommended dosage. Tolerance to the bronchodilator response does occur, but the degree is not usually clinically significant unless these agents are used excessively. Such abuse is more likely to occur with the metered-dose inhaler with occasional serious consequences.

Stanley P. Galant, M.D.
Orange, California

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Treatment of Hypertriglyceridemia

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At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

Major advances in the understanding and definition of the hyperlipidemias have occurred over the past 15 years. Treatment of the common forms of hyperlipidemia including hypertriglyceridemia is often undertaken to prevent atherosclerotic cardiovascular disease, although current data do not definitively demonstrate that such therapy achieves its objectives. It is possible to normalize or substantially reduce elevated triglyceride levels in the majority of individuals using dietary intervention and/or medications. The frequency with which hypertriglyceridemia is diagnosed in the population, the controversy concerning the association of plasma triglyceride levels and cardiovascular disease, and the potential need for life-long therapy has made consideration of this topic timely.

To resolve some of these questions, the National Institutes of Health convened a Consensus Development Conference on the treatment of hypertriglyceridemia on September 27-29, 1983. After a day and a half of expert presentation of the available data, a Consensus Panel consisting of lipidologists, cardiologists, primary care physicians, epidemiologists, and experts in exercise considered the evidence and agreed on answers to the following questions:

1. What is hypertriglyceridemia?
2. What is the evidence that plasma triglycerides are associated with disease?
3. What patients with hypertriglyceridemia are candidates for therapy?
4. What can be achieved with dietary and other therapies?
5. What should be guidelines for dietary and drug therapy?
6. What should be the direction for future research?

Conclusions

Careful evaluation of existing data indicates that in the presence of normal cholesterol levels mild elevations of plasma triglycerides do not necessarily increase the risk of cardiovascular disease. When triglycerides are below 250 mg/dl risk generally does not exceed that of other Americans, and changes in lifestyle are unnecessary beyond those recommended for the general public. The same can be said for many normocholesterolemic individuals with borderline hypertriglyceridemia who have no risk factors or family history for cardiovascular disease. However, triglyceride levels in the range of 250 to 500 mg/dl can be a marker for secondary disorders for a subset of patients with genetic forms of hyperlipoproteinemia who are at increased risk and who need specific therapy. Dietary intervention is the primary approach to therapy in these patients, but drugs have a role in selected individuals not responding to dietary management. Finally, the danger of pancreatitis is present in frank hypertriglyceridemia (triglycerides > 500 mg/dl), and triglyceride lowering by diet and, if necessary, by drugs is indicated.

1. What is hypertriglyceridemia?

Triglycerides are lipid molecules derived from dietary fat or endogenous synthesis. They are transported from

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the intestine and liver within plasma lipoproteins to tissues for use as fuel or to adipose tissue for storage. After an overnight fast, they are normally found predominantly as part of triglyceride-rich very low density lipoproteins (VLDL).

Fasting levels of plasma or serum triglycerides are distributed across a broad range in apparently healthy populations. Median and 95th percentile levels tend to be higher and to increase with age in western industrialized societies compared to other cultures, a difference that parallels obesity patterns. Because triglyceride levels have a continuous distribution, the distinction between "normal" and "abnormal" is arbitrary. The levels suggested here are based on their ability to act either as a marker for an existing metabolic abnormality or to predict a significant excess risk of subsequent disease, rather than on some reference level above the mean or median value in the population. The following levels are suggested to guide physician management only, and do not imply that disease will inevitably follow or that intervention will necessarily prevent disease.

Fasting plasma triglyceride levels above 1,000 mg/dl carry a significant risk of pancreatitis. Based on this risk coupled with the large intraindividual variation in repeated triglyceride measurements, a triglyceride level greater than 500 mg/dl is considered to be abnormal, and warrants the label hypertriglyceridemia.

There is little evidence that triglyceride levels below 250 mg/dl in the presence of normal cholesterol levels predict an increased risk of any disease. These levels can be considered normal, although it is recognized that some persons with thus-defined normal triglyceride levels may have other significant lipoprotein or apoprotein abnormalities.

Persons with fasting plasma triglycerides between 250 and 500 mg/dl represent a different problem, because in the aggregate such levels are associated with an approximate twofold excess risk of cardiovascular disease. In an individual patient, these triglyceride levels may be normal or a marker for increased risk. If these borderline levels are confirmed by repeated measurement they warrant further investigation in a patient who has a family history of premature cardiovascular disease (such as myocardial infarction in a first-degree relative before age 55), other heart disease risk factors such as high cholesterol levels, hypertension, cigarette smoking, obesity, or a secondary cause for elevated triglycerides as listed in Section 3. Some of these persons will be found to have a dyslipoproteinemia, and others will ultimately be considered normal.

2. What is the evidence that plasma triglycerides are associated with disease?

The link between triglyceride levels and disease is most clear for severe hypertriglyceridemia associated with chylomicronemia and eruptive xanthomata, abdominal pain, and/or pancreatitis; the latter, although uncommon, can be fatal. This relationship is believed to be direct and the disease consequences preventable by triglyceridemia reduction.

The relationship between triglyceride and cardiovascular disease is more controversial but potentially of greater relevance to public health and to clinical practice. Although triglyceride levels are positively associated with an increased risk of cardiovascular disease in most prospective population studies, much of the recent controversy about their importance stems from the finding that they are not independently predictive after statistically adjusting for closely associated attributes such as obesity, total cholesterol, high density lipoprotein (HDL) cholesterol, hypertension, and cigarette smoking. These data suggest that triglyceride, rather than contributing directly to the risk of cardiovascular disease, is a marker for other lifestyle or metabolic characteristics or genetic lipoprotein disorders. Other observations that support a lack of a causal association between triglyceride and cardiovascular disease include the absence of premature cardiovascular disease in some persons with familial hypertriglyceridemia or with chylomicronemia.

On the other hand, almost all case control studies of survivors of myocardial infarction have shown higher triglyceride levels in the affected patients. Similarly, many diseases associated with high triglyceride levels, such as diabetes mellitus, chronic renal disease, and certain primary hyperlipidemias, are associated with an increase in risk for cardiovascular disease. Moreover, plasma triglyceride levels between 250-500 mg/dl may be a marker for lipoprotein abnormalities that are more directly associated with atherosclerosis such as low HDL-cholesterol, low apoprotein A-I, and high apoprotein B levels. Alternatively, these triglyceride levels may reflect the presence of triglyceride-rich lipoprotein particles and/or their metabolic products that may be directly involved in processes associated with enhanced atherogenesis.

Whether triglycerides are directly involved in the atherogenic process, elevated levels sometimes can be helpful for identification of persons with increased risk of cardiovascular disease.

3. What patients with hypertriglyceridemia are candidates for therapy?

Candidates for management of hypertriglyceridemia include those patients with primary and secondary hyperlipoproteinemia.

Secondary Hyperlipoproteinemia

Much of the hypertriglyceridemia seen in clinical practice is secondary to a variety of exogenous factors or clinical disorders. This category is defined as secondary hyperlipoproteinemia. The most common secondary factor raising triglyceride levels is obesity. It is probably the major cause of mild elevations of plasma triglycerides, and triglyceride levels frequently normalized following restoration of desirable weight. Other conditions raising the plasma triglycerides include excessive alcohol intake, and the use of a variety of drugs including thiazide diuretics, oral contraceptives and other estrogens, and some beta-adrenergic blocking drugs. Clinical conditions associated with high plasma triglycerides include: diabetes mellitus, hypothyroidism, renal disease (uremia, nephrotic syndrome, maintenance dialysis, renal transplantation), liver disease, dysproteinemias, and occasionally other metabolic and endocrine diseases. Acute stress states such as burns, trauma, myocardial infarction, and sepsis may also induce hypertriglyceridemia. If hypertriglyceridemia persists despite management of the underlying condition, consideration must be given to the possibility that the patient has a primary form of hyperlipoproteinemia such as familial hypertriglyceridemia.

Primary Hyperlipoproteinemia

It is convenient to classify primary hyperlipoproteinemias that are associated with plasma triglyceride elevations into two categories, depending on the concentration of serum triglycerides. These are distinct hypertriglyceridemia (triglycerides greater than 500 mg/dl) and borderline hypertriglyceridemia (triglycerides 250-500 mg/dl).

Hypertriglyceridemia: Patients with triglyceride levels between 500 and 1,500 mg/dl (Type IV or mild Type V hyperlipoproteinemia) sometimes accumulate chylomicrons and can develop pancreatitis. Probably less than 1 in 1,000 persons have triglycerides over 500 mg/dl. Opinion is divided as to whether such levels are associated with increased risk for cardiovascular disease in the absence of other risk factors, but triglyceride levels should be reduced in any event to prevent pancreatitis.

Marked elevation of serum triglycerides (>1,500 mg/dl) occurs in two forms. In both, the risk for acute pancreatitis is high and immediate attention must be given to lowering triglyceride levels. The first form (Type I hyperlipoproteinemia) is a very rare condition characterized by an increase in chylomicrons alone. It is due to a deficiency of lipoprotein lipase and is manifest in childhood. The second form is severe (Type V hyperlipoproteinemia), characterized by an increase in chylomicrons and VLDL; it is relatively uncommon and occurs most often in adults. In many cases diabetes mellitus is present, although there is usually an underlying primary disorder of triglyceride metabolism.

Borderline Hypertriglyceridemia: The triglyceride levels in this category range between 250 and 500 mg/dl. Five to 10 percent of adult Americans have triglyceride levels in this range. In the absence of elevated serum cholesterol (in the individual or family members), other risk factors for heart disease, or premature cardiovascular disease in other family members, there is no evidence for increased cardiovascular risk; specific triglyceride-lowering therapy seems unnecessary. If the individual has other major risk factors, such as hypertension, smoking, or obesity, vigorous attempts to modify these factors should be undertaken.

One genetic form of hyperlipidemia in which triglyceride levels can be mildly elevated is familial combined lipidemia. Affected individuals of one family can have various lipoprotein phenotypes—Type IV (increased VLDL), Type IIA (increased low density lipoproteins [LDL]), or Type IIB (increased VLDL and LDL). One individual can demonstrate different phenotypes at different times, and risk for cardiovascular disease is increased regardless of the lipoprotein pattern. Patients with familial combined hyperlipidemia deserve attempts at lipid lowering, with diet first and, if necessary, with drugs. Any patient with borderline hypertriglyceridemia who already has clinical manifestations of premature cardiovascular disease can be treated as if he/she has familial, combined hyperlipidemia.

Another group of patients with increased risk of cardiovascular disease has the relatively rare entity, familial dysbetalipoproteinemia (Type III hyperlipoproteinemia). This condition is an inherited disorder characterized by the accumulation of catabolic remnants of VLDL and chylomicrons. Consequently, plasma levels of both triglycerides and cholesterol are increased, and occasionally, triglyceride concentrations may exceed 500 mg/dl. Dietary and/or pharmacologic intervention as well as treatment of any concomitant clinical disorder should be instituted.

4. What can be achieved with dietary and other therapies?

Changes in lifestyle—weight control, increased physical activity, alcohol restriction, and fat restriction—are primary therapy for reducing elevated triglyceride levels.

Weight Control: In overweight persons with elevated triglycerides, the primary goal of therapy is achieving and maintaining desirable weight. Weight loss and maintenance of desirable weight will decrease plasma VLDL and triglycerides, often to normal levels, and at the same time it will increase HDL-cholesterol. Lower triglyceride levels generally are maintained in the steady state at reduced levels. Treatment by caloric restriction should emphasize decreased intakes of fats, especially saturated fats. A reduction in dietary saturated fats not only facilitates weight loss but also promotes cholesterol lowering.

Increased Physical Activity: In most training studies, acute and long-term increases in aerobic exercise cause a substantial decrease in plasma triglycerides except in individuals who already have low normal levels. Adoption of a prescribed exercise program is usually accompanied by other advantageous changes: an increase in HDL-cholesterol; a rise in apolipoprotein A-I; and an increase in activity of lipoprotein lipase. Most individuals who adopt and maintain a program of progressive aerobic exercise also lose and then stabilize body weight.

Alcohol Restriction: In some persons, triglyceride levels are particularly sensitive to alcohol. In these individuals alcohol intake should be restricted.

Fat Restriction: If achieving desirable weight, alcohol reduction, and exercise do not produce a satisfactory lipid lowering, further alteration of diet must be considered. The next step is to progressively reduce saturated fat and cholesterol. For the person already at desirable weight, removal of saturated fats requires replacement by other calories. Substitution by carbohydrates generally is favored; although increasing the carbohydrates in the diet may raise triglycerides, the response usually is transient, and triglyceride levels later decline.

5. What should be the guidelines for dietary and drug therapy?

Dietary therapy is the primary approach to treatment of hypertriglyceridemia. The combination of weight control, exercise, alcohol restriction, and reduction of fat intake should be used to the fullest extent possible before considering drug therapy. In patients who do not respond satisfactorily to physician guidance, the assistance of a trained dietitian can be helpful. Since people may require a considerable period of time to adjust to diet modification, a precipitous decision to use drugs should not be made. Except in cases of severe chylomicronemia in which danger of pancreatitis is high, several months a year may be taken to allow for the full benefits of diet before resorting to drugs. Even if the response to diet is considered inadequate, drug therapy should be employed only under certain circumstances. Persistence of hyperlipidemia first must be documented in multiple measurements (usually three) before starting drugs. Without question, use of drugs can be helpful in some patients to prevent development of pancreatitis. However, drugs should be employed for prevention of atherosclerotic disease only if a favorable response can be demonstrated in the plasma lipids—at the minimum a significant lowering of plasma total cholesterol as well as triglycerides. Therefore, the therapeutic response must be monitored, and drugs should be discontinued if the response is inadequate.

Diet In Specific Disorders

Hypertriglyceridemia: In the presence of severe chylomicronemia, very low fat diets (10 to 20 percent of total calories) may be required to prevent pancreatitis. Dietary therapy is the only available treatment for Type I hyperlipoproteinemia. In other forms of chylomicronemia (hyperlipoproteinemia, e.g., severe Type V), fat restriction often is successful in lowering triglycerides to a safe range. The need to maintain a very low fat intake *at all times* must be emphasized. Some patients are extremely sensitive to dietary fat and may develop acute pancreatitis with a single high-fat meal. In some patients, repeated bouts of pancreatitis occur despite all attempts at dietary control. In such patients, or in others who persistently have severe chylomicronemia, a trial with drug therapy is justified.

Borderline Hypertriglyceridemia: With familial combined hyperlipidemia, hypertriglyceridemia often is accentuated by obesity, and weight control therefore is the first goal of therapy. Furthermore, the composition of the diet should be modified to restrict fat intake to 30 percent of calories, saturated fats to less than 10 percent, and cholesterol to 300 mg/day. If these changes do not normalize the plasma lipids, further restriction of dietary fat may be needed. An alternative to severe fat restriction is use of drugs, as will be discussed below.

In familial dysbetalipoproteinemia, the same approach can be used as with familial combined hyperlipidemia. Dietary therapy often is very successful in lowering triglycerides in patients with dysbetalipoproteinemia, but again, drugs may be required.

Secondary Hyperlipidemia: In most secondary hyperlipoproteinemias the first step is to treat the underlying disorder. In some instances, lipid lowering may be facilitated by modification of the diet. This will usually involve weight reduction and alcohol restriction. Again, it should be emphasized that obesity is the most common cause of borderline hypertriglyceridemia, and triglyceride levels often can be normalized completely by weight reduction.

Drugs In Specific Disorders

As indicated above, drug therapy in hypertriglyceridemia should take a second place to modification of the diet. Drugs nevertheless may be required to avoid abdominal pain and pancreatitis in the presence of chylomicronemia. They also can be used to produce regression of xanthomata in patients of this kind or in those with familial dysbetalipoproteinemia. Drugs also may be employed in the attempt to retard atherogenesis in patients with genetic hyperlipidemias, such as familial combined hyperlipidemia or familial dysbetalipoproteinemia, or in those with established cardiovascular disease. It must be emphasized, however, that a definitive clinical trial has never been carried out to determine whether drug therapy will cause a decrease in the morbidity and mortality from cardiovascular disease in any form of hypertriglyceridemia.

The three currently approved drugs, which are generally recognized as being effective in lowering triglycerides, are clofibrate, gemfibrozil, and nicotinic acid. Experts do not agree on the drug of choice.

The rational choice of drugs requires knowledge of their pharmacokinetic properties and their adverse effects or toxicity. Clofibrate administration is associated with few overt side effects, but cholethiasis, myalgias, and in rare instances, ventricular arrhythmias have been reported. In a large clinical trial to assess the efficacy of clofibrate in individuals with hypercholesterolemia, an increase in drug-associated mortality was reported that offset the beneficial response to cholesterol lowering;

therefore, the potential dangers of this drug must be kept in mind when prescribing it for patients with hypertriglyceridemia. Also, a lowering of triglycerides by clofibrate often is associated with an increase in LDL levels, a response that has caused many to question whether any net gain is achieved in overall lipoprotein metabolism.

There is limited clinical experience with a related drug, gemfibrozil, which has many of the actions of clofibrate. Again, triglyceride reduction can result in a rise in LDL levels. The side effects of gemfibrozil resemble those of clofibrate, although effects on overall mortality in a large population have not been defined.

Flushing and pruritus are significant early side effects of nicotinic acid administration, but most people develop tolerance. A variety of other skin changes have been noted. More severe side effects of nicotinic acid are hyperuricemia, hyperglycemia, and hepatic function abnormalities, but these are more frequent with higher doses. Gastrointestinal complaints are also common.

Hypertriglyceridemia: Drug therapy is of no benefit in familial lipoprotein lipase deficiency in children. When drugs are employed for Type V hyperlipoproteinemia, clofibrate or gemfibrozil generally are used first, followed by nicotinic acid if one of these is ineffective. Drug therapy is frequently ineffective if secondary causes of hypertriglyceridemia are not controlled.

Borderline Hypertriglyceridemia: In familial combined hyperlipidemia, nicotinic acid would seem to be the preferred drug if there are no contraindications and if the drug can be tolerated. These patients are more likely to have an increased LDL concentration, and nicotinic acid is usually more effective in lowering LDL than clofibrate or gemfibrozil. Combination therapy is occasionally indicated; the combination of a bile-acid sequestering agent (cholestyramine or colestipol) with nicotinic acid probably would normalize both cholesterol and triglyceride levels in most patients. The bile-acid sequestering agents may significantly increase plasma levels of triglycerides when they are not used with a triglyceride-lowering agent.

In familial dysbetalipoproteinemia, the predominant experience has been with clofibrate, which is generally very effective. Limited experience with gemfibrozil and nicotinic acid suggests that they too are effective.

Secondary Hyperlipoproteinemia: Lipid-lowering drugs have occasionally been used in patients with chronic renal disease or diabetes mellitus. Route of elimination, serum albumin concentrations, and likelihood of producing hyperglycemia or hyperuricemia are special considerations in choice of drug and dosage.

6. What should be the direction for future research?

Certain changes in concentrations, composition, or structure of plasma lipoproteins are reflected as increased plasma triglyceride concentrations and appear to be associated with increased risk for cardiovascular disease. There is need to intensify research in several areas to understand better the pathophysiologic mechanisms responsible for increased atherogenesis in these conditions. Also among the areas of needed research are determination of the epidemiologic implications of elevated triglyceride concentrations, laboratory approaches to the evaluation of hypertriglyceridemic patients, the pathogenetic mechanisms by which triglyceride-rich lipoprotein particles may influence atherogenesis, and approaches to the treatment of metabolic disorders resulting in hypertriglyceridemia.

Epidemiologic Considerations: There are three major areas of needed epidemiologic research. The first concerns the need to investigate reasons for the relatively high plasma triglyceride concentrations and the age-related increases observed in the United States compared to some other countries. For example, it would seem important to determine the degree to which age-related increases in plasma triglycerides are a function of obesity. The second need is to evaluate the impact of commonly used drugs (such as antihypertensives) on plasma lipid and lipoprotein distribution in population studies. The third need is for improved study design for estimating risk for cardiovascular disease from elevated triglycerides, particularly in subjects characterized by repeated triglyceride measurements. Subgroups of particular interest are those with genetic abnormalities of lipoprotein metabolism. Such studies should clarify the specific risks and perhaps resolve the current conflict between epidemiologic and clinical observations.

Laboratory Evaluations: The extent to which hypertriglyceridemia is a risk factor for cardiovascular disease seems to depend, among other things, on other characteristics of the plasma lipoproteins. Particular attention should be given to the linkage between hypertriglyceridemia and subclasses of LDL and HDL and specific apoproteins (e.g., apo A-I and apo B). More research is needed to identify better which of these measurements best classifies the cardiovascular disease risk associated with hypertriglyceridemia. More methodologic research is called for to simplify the measurements of lipoprotein subclasses and apoproteins and thus make them more readily available to the clinician.

Pathogenetic Mechanisms of Atherogenesis: The pathogenetic mechanisms by which triglyceriderich lipoproteins may influence atherogenesis have received little research attention in the past and research efforts should be intensified in the future. A few of the important research directions include:

- Does the process of VLDL degradation at the level of the artery wall generate products that contribute to atherogenesis (cholesterol, free fatty acids, lysophospholipids)?
- What is the importance of abnormal lipoproteins in the pathogenesis of human atherosclerosis?
- Do the heterogeneous properties of VLDL particles (reactivity with cell surface receptors, apolipoprotein

content, or distribution) determine their atherogenicity?

- Using appropriate animal models, what interactions can be found among the characteristics of the triglyceride-rich lipoproteins, smoking, and the development of atherosclerosis in the coronary and the peripheral arteries? Attempts to establish interactions between smoking and diet-induced hyperbetalipoproteinemia in experimental animals have been negative. Clinical evidence suggests that the association between smoking and increased concentrations of the triglyceride-rich lipoproteins may be stronger.
- There is need to develop colonies of experimental animals with hypertriglyceridemia.

Therapeutic Approaches: Nutritional approaches to the treatment of hypertriglyceridemia have not been studied sufficiently. The promising initial finding of lowering effects of VLDL and LDL by fish oil-containing diets needs additional research to understand better the mechanisms, the clinical potential, and the long-term safety of such diets.

New quantitative noninvasive and invasive techniques for measuring arterial flow and atherosclerotic lesion size (and luminal impingement) should be employed to determine more directly the effects of hygienic and pharmacologic interventions. Coronary artery bypass grafts offer a promising opportunity to examine the effect of triglyceride lowering on graft occlusion.

While there are several drugs available that affect triglyceride metabolism there is a continuing need for drugs with greater potency, minimal or no adverse effects on LDL and HDL, and fewer side effects.

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Members of the Consensus Development Panel were: Scott M. Grundy, M.D., Ph.D., (Panel Chairman), Professor, Internal Medicine and Biochemistry, Director, Center for Human Nutrition, University of Texas Health Science Center, Dallas, Texas; Elizabeth Barrett-Connor, M.D., Dr.P.H., Professor, Department of Community and Family Medicine, University of California, San Diego, La Jolla, California; Edwin L. Bierman, M.D., Professor of Medicine Head, Division of Metabolism, Endocrinology, and Nutrition, University of Washington, Seattle, Washington; Thomas B. Clarkson, D.V.M., Professor of Comparative Medicine, Director, Arteriosclerosis Research Center, Bowman Gray School of Medicine, Winston-Salem, North Carolina; William R. Harlan, M.D., Professor of Internal Medicine, University of Michigan School of Medicine, Ann Arbor, Michigan; William R. Hazzard, M.D., Associate Director, Department of Medicine, Johns Hopkins Medical School, Johns Hopkins Hospital, Baltimore, Maryland; Donald B. Hunninghake, M.D., Associate Professor of Pharmacology and Medicine, Co-Director, Lipid Research Clinic, Department of Medicine, University of Minnesota, Minneapolis, Minnesota; Dean T. Mason, M.D., Director, Cardiac Center, Cedars Medical Center, Miami, Florida; Gregory O'Keefe, M.D., Islands Community Medical Center, Vinal Haven, Maine; Harold Rifkin, M.D., Clinical Professor of Medicine, Albert Einstein College of Medicine, New York, New York; Arthur A. Spector, M.D., Professor of Biochemistry, Department of Biochemistry, University of Iowa, Iowa City, Iowa; Mary Winston, Ed.D., Science Administrator, Medical Programs, American Heart Association, Dallas, Texas; Peter D. Wood, D.Sc., Ph.D., Professor of Medicine, (Research), Deputy Director, Stanford Heart Disease Prevention Program, Palo Alto, California.

Members of the Planning Committee were: Basil M. Rifkind, M.D., F.R.C.P. (Chairman), Chief, Lipid Metabolism-Atherogenesis Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland; H. Bryan Brewer, Jr., M.D., Chief, Molecular Disease Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland; John D. Brunzell, M.D., Professor of Medicine, Division of Metabolism, Endocrinology, and Nutrition, University of Washington, Seattle, Washington; Scott M. Grundy, M.D., Ph.D., Professor, Internal Medicine and Biochemistry, Director, Center for Human Nutrition, University of Texas Health Science Center, Dallas, Texas; Lewis H. Kuller, M.D., Dr.P.H., Professor and Chairperson, Department of Epidemiology, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania; Fitzhugh Mullan, M.D., Chief Medical Officer, Office of Medical Applications of Research, National Institutes of Health, Bethesda, Maryland; Gary Nelson, Ph.D., Health Scientist, Administrator, Lipid Metabolism-Atherogenesis Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland; Pesach Segal, M.D., Expert, Lipid Metabolism-Atherogenesis Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland.

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The Rising Cost of Health Care: An Issue Brief

FRANKLIN ROBINSON, M.D. AND MARK A. MEISTER, M.A.

ABSTRACT—The cost of medical care is a topic of considerable discourse among our nation's political leaders and social planners. Rather than focusing on and understanding the necessary components of our national health care expenditures, we have typically treated this complex social issue with simplistic economic measurements followed by unenlightened "knee-jerk" reactions. Corporate, consumer and political cost control advocates champion a cause which suggests that it is morally wrong to spend a certain percentage of our economy's output on society's health and well-being. The most fundamental debate is yet to be heard; and that is, exactly how much *should* we spend on one of our nation's most valuable resources. When a member of Congress recently requested our county medical society's opinion on the matter of rising health care costs, we realized that a statement on the issue had not yet been formally adopted. The following issue brief represents a formal statement on the economic factors impacting medical care in our country. The intent of this issue brief is not to delineate solutions to a so-called problem, but rather to educate and inform so that this pressing social issue can be approached in a constructive, rational manner.

Overview

In his April 28, 1984 Walter L. Bierring lecture, the former president of the AMA, Frank J. Jirka, Jr., M.D., stated that, "... without any serious question, (American medical care) is the best and most accessible medical and health care system in the world."[1] While few in our society would dispute this claim, there is growing concern that American medical care is on the verge of economic crisis. With total expenditures approaching $1 billion a day, many in our society believe our country is spending too much on medical care. A recent report on national health expenditures reveals that our society spent $322 billion for health care in 1982, the most recent year for which complete information is available.[2] Other 1982 statistics cited in the report indicate that health care expenditures equalled 10.5% of the GNP, amounting to $1,365 for each person in our country.

Health care costs are undeniably high. But exactly how much, we must ask, is the right amount to invest in one of our nation's most valuable resources: the health of its people? As physicians representing all spectrums of medical science in our community, the New Haven County Medical Association is today, as it has been throughout its 200 year history, committed to the basic principle that medical care should be provided in the most efficient and effective setting possible, consistent with professionally recognized standards of quality patient care. It is within the context of this commitment, that we offer this formal statement on the economic factors, which affect the delivery of medical care in America.

The Health Care Dollar

To begin, it is important to recognize where the health care dollar is going in terms of how much is being spent on various components within the health care delivery system. The following table, taken from a 1982 study on our national health expenditures presents this information by type of expenditure, dollar amount and percentage.

Type of Expenditure	*Total Expenditure*	*Total Percentage*
	$	%
Health Services and Supplies	$308.3	95
Personal Health Care	286.9	89
Hospital Care	135.5	42
Physicians' Services	61.8	19
Dentists' Services	19.5	2
Other Professional Services	7.1	2
Drugs and Medical Sundries	22.4	7
Eyeglasses and Appliances	5.7	2
Nursing-Home Care	27.3	8
Other Health Services	7.6	2
Program Administration and Net Cost of Insurance	12.7	4
Government Health Activities	8.6	3
Research, and Construction of Medical Facilities	14.1	5
Research	5.9	2
Construction	8.2	3
TOTAL	$322.4	100

Source: Gibson, Robert M., et al, "National Health Expenditures," 1982 *Health Care Financing Review* (Fall 1983/Volume 5, November 1).

FRANKLIN ROBINSON, M.D., President, New Haven County Medical Association; Clinical Professor of Neurosurgery, Yale University School of Medicine; Attending Neurosurgeon, Yale New Haven Hospital; Section Chief, Neurosurgery and Attending Neurosurgeon, The Hospital of St. Raphael. MARK A. MEISTER, M.A., Executive Director, New Haven County Medical Association, Woodbridge, CT.

As evidenced by these statistics, our national health care expenditures encompass much more than what is customarily considered to be conventional medical care, i.e., a few visits to the doctor's office and an occasional hospitalization. Total health care spending, it must be emphasized, embraces all goods, services, facilities, administration and research required to operate and sustain a social system charged with the responsibility of meeting the health care needs of over 234 million Americans.

Contributing Factors

Social Expectations

Next, the degree to which the demand for health care resources has historically influenced the increasing costs of our medical system must be considered. We as a society have certain expectations with regard to health. Society's perception of health care as a basic right has resulted in immense demand for the resources necessary to respond to such expectations.

The federal government reaffirmed this social commitment to the nation's health and well-being over 30 years ago through the passage of the Hill-Burton Act, which funneled millions of dollars into the construction and expansion of our nation's hospitals. The passage of the Medicare and Medicaid program in 1965 likewise had a direct effect upon the demands placed on the health care delivery system as it provided millions of dollars for increasing society's access to medical care. A more recent phenomenon, but of comparable significance, has been private industry's growing provision of comprehensive, first-dollar insurance programs to all employees and family members to cover all imaginable medical or health care needs, without financial obligation by the patient.

Medical Technology

Another major factor contributing to increased demand for health care resources is the proliferation of sophisticated technology in the care and treatment of disease. Medical technology has played a key role in translating the desire for improved health status into increased demand for health care services. The availability of medical technology, such as renal dialysis, for example, has resulted in the increased use of such technology, which not only prolongs and enhances life, but also drives up the overall costs of medical care.

Demographics

The changing demographics of our society is another important element in the increasing demand for health care services. According to a recent census bureau report, one of the most significant factors affecting American society is the aging of its population. Statistics from this report reveal that the number of persons aged 65 and older in our society is expected to double within 40 years, comprising over 14% of the entire population.[3] Increased delivery of health care services and, correspondingly, increased health care spending, has resulted as it becomes necessary to meet the needs of an aging population.

Inflation

While our growing demand for health care resources is a major contributor to increasing health care expenditure levels, it is also important to recognize the extent to which general inflationary trends have likewise compounded this situation. Again referring to the 1982 study on expenditures, we find that health care expenditures increased by $32 billion or 12.5% from 1981 to 1982. During this period, it was found that, of this additional $32 billion, $16.5 billion (51%) was due to general inflation of the economy, $8.6 billion (27%) resulted from price inflation within the health care system, $2.5 billion (8%) was due to population growth and the remainder was attributed to the aging of our population, per capita increased consumption of health care services, and changes in the types and nature of the services provided.

Soaring business costs associated with operating health care facilities and physicians' offices have significantly contributed to medical care price inflation. Health care, despite its remarkable technological advances, is very labor-intensive and is considered to be among the slower segments of our economy in terms of productivity growth, making it particularly susceptible to rapid price inflation. In addition, business expenses incurred by physicians are reflected in the overall increase in medical care price inflation. AMA figures indicate that from 1973 to 1982 physician expenses rose 143%, compared to a 51% increase in physician net income.[4]

Professional Liability Costs

As one of the major components of the physician's cost of operating an office, increased professional liability insurance premium costs have soared to almost inconceivable heights. Historically, the trend toward more liberal malpractice settlements increased insurance premiums by 600% for physician coverage and 900% for surgeons from 1960 to 1972.[5] This trend continues today. In June of 1984, the insurance carrier for the medical association-sponsored professional liability program in Connecticut, CNA, announced an increase of over 40% in insurance premium costs for the 1984-85 program year. A phenomenon known as "defensive medicine" has also contributed to the overall increase in medical care costs. To reduce the potential of future malpractice claims, many physicians practice defensive medicine by increasing their use of laboratory tests and x-rays to protect themselves against legal "hindsight" with regard to ways in which a case might have been handled differently. In testimony before a Senate panel on July 10, 1984, James E. Davis, M.D., speaker of the AMA House of Delegates, suggested that the practice of defensive medicine accounts for approximately $15 billion in increased medical costs per year.[6]

What Can Be Done

Much of what is responsible for the increase in medical costs is clearly outside the direct influence of the physician-providers of medical care. We must objective-ly consider therefore the health care cost issue in the context of those factors which contribute significantly to total health care expenditures, namely, the demand for health care resources and inflationary trends in the economy. When so doing, it becomes evident that this issue is one of broad concern and one in which society at large must participate, if we are to arrive at a sensible approach to meeting our health care needs in an environment of rising costs and limited resources. Unilateral attempts by the government and industry to regulate health care through cost controls and alternative financing methods can only lead to diminished access to needed health care services or, in other words, rationing of medical care. Plans for reducing health care costs are being trumpeted to the public as an unqualified good, particularly for those who have difficulty affording health care—the elderly and the poor. The facts are that efforts in this area will cut costs by diminishing the health care that is available to the elderly and the poor. Unfortunately, these social groups are being sold a political position that is inherently erroneous and ultimately detrimental to society's health and well being.

What is needed to effectively address this issue of such complexity is a carefully planned and coordinated long-term strategy that will successfully stem the spiral of rising health care costs, while assuring that the access to medical services and the quality of our nation's health is not compromised. NHCMA supports many of the solutions currently in place and working to this end, including medical peer review, redesign of insurance benefits and the funding of alternative health care delivery systems making for competition in the so-called market place rather than a national health system.

There are other areas, however, requiring far greater emphasis and consideration. Among these, legislative reform relating to professional liability is essential for successful control of health care expenditures. As already indicated, professional liability costs are among the most serious concerns facing the future of American medicine. No segment of litigation within our legal system has had a more rapid increase during the past fifteen years than claims emanating from health care. What is urgently needed is tort reform governing the settlement of valid professional liability claims. Specifically, an alternative system for the settlement of claims should be created, which would fairly compensate for personal injury suffered and would foreclose the possibility of future civil action once an offer for compensation has been made. Such a system would limit the number of cases subject to lengthy court adjudication, reducing the tremendous backlog of cases pending and the cost of litigation. In addition, the incentives to practice defensive medicine would be reduced and malpractice premiums would be contained within reasonable limits, reducing the overall costs of medical care.

Finally, we must all become better informed of the complexity of the health care cost issues. Community organizations and professional societies, such as NHCMA, must play a greater role in educating society in this regard as well as in the promotion of healthy lifestyles and physical fitness. Preventive health measures such as control of obesity, hypertension, drug and substance dependence, and accidents, to name a few must be practiced and stressed by the medical profession and its societies. Physicians should educate their patients in the appropriate use of health care facilities and encourage cost consciousness on the part of all who use the health care system. In addition, the economics of health care and efficient medical practice techniques must be emphasized in medical school curriculum and the training of our young physicians.

Conclusion

NHCMA was pleased to submit this issue brief in an effort to communicate a formal statement on the economic factors impacting our medical care system. As physicians involved in medical care delivery, administration and education in our community, we believe that the first and perhaps most significant step that can be taken to establish an effective health care cost strategy for the future, is communication. We must approach this matter together in a spirit of openness and cooperation as we strive for a common goal: the furtherance and protection of our society's health and well-being.

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Responsibility for Quality Health Care in an Age of Cost Containment

JOHN J. PARIS, S.J.

This morning's *New York Times* contains an item on the American Medical Association's conference being held in Chicago. A startling aspect is that for the first time the AMA is backing an increase in taxes on alcohol and tobacco to provide money for the insurance/hospital trust fund of Medicare. The medical profession, acutely aware of the financial crisis facing the Medicare and Medicaid systems, is now proposing ways to provide more money for the Medical system.

In addition to proposing new taxes, what is more startling is that the delegates voted that it would be "inappropriate" for the American Medical Association to develop guidelines for "the rationing of health care." Cost containment, DRG, Chapter 372, Capping . . . these are the issues which you are certainly more familiar with than I. Yet, it is here that the AMA is saying it is not up to them—the health care professionals—to attempt to develop guidelines. If medicine wants to stay in control of its own house, if the community and this profession want to have a voice in the direction in which medicine is delivered, then it is encumbent upon you to help formulate the guidelines which will inevitably be promulgated in this area.

That responsibility, despite the AMA's stand on rationing decisions, cannot be abandoned by medicine. Nor can medicine perpetuate the notion that—despite the reality of ever-spiraling costs—that its only commitment is to the best care for the patient. Speaking to that subject in an essay entitled, "The Doctor's Dilemma and Society's Too" in the March 15 issue of *The New England Journal,* Dr. Alexander Leaf described the problem that he, as a physician, is now confronting. On the one hand, he says, he is committed by oath to single-mindedly serving as the patient's advocate—being concerned only about the quality of care the patient receives—and on the other he is now being told that he must consider cost as well. "How," he legitimately asks, "does one resolve this clash of values?"

And a clash it is. Speaking to that topic in the April 12 edition of *The New England Journal,* Bruce Spivey describes the relationship between hospital management and medical staff under a prospective payment system as "a bloodbath." The administrators are concerned with costs and the financial integrity and viability of the institution while the physician has as his or her primary goal "the best interests" of the patient without concern for cost.

This is a rather interesting and somewhat new phenomenon. Back in the '50s, when I was growing up as a poor boy in Boston, while every other kid in Scarsdale or Fairfield might have braces, there wasn't one in the South End who had ever heard of an orthodontist. I don't think that when the dentists were making their decisions as to who did or did not get braces, that the sole determinant was the best interest of the patient, cost being an indifferent factor.

Yet just a week ago, I heard a neonatologist, from one of the world's leading medical centers, tell a state-wide conference that in pediatric care, particularly in neonatology, cost is not and cannot be a consideration. That theory is repeated in an article I recently reviewed for one of the major medical journals. The case involved a child born with multiple problems and maintained for several months in the ICU. The bill for his care was $107,000. The attending physician commented, "I was stunned by the size of that bill, but as a physician, I could never consider cost in the way I treat my patients. I simply had an obligation to use all of the resources available, regardless of the cost." The costs he was discussing were not even particularly high for neonatology. One of the cases investigated by the Infant Doe squads entailed a bill of over $400,000, and I was recently at a hospital in Cincinnati where they told of a child who died after nearly a year in the Intensive Care Unit whose total bill exceeded $852,000.

If we go that route, if every practitioner believes that he or she can use all the available resources indifferent to the final outcome, then we will all be the losers.

Today we are beginning to understand what Dean Howard Hiatt of the Harvard School of Public Health, highlighting Garret Hardin's famous "Tragedy of the Commons" essay meant when he warned as far back as 1975 that if we follow the "hang the cost" philosophy and allow each physician or sub-specialty to demand more and more, that eventually we will deplete the Commons and all will suffer. With health care consuming over 10.8% of the Gross National Product, the business community—and now the taxpayers—say that we have reached that point where there is no escaping the dictates of the bottom line, the point where we must say, "STOP."

What does this mean in practical terms for health care

JOHN J. PARIS, S.J., Associate Professor of Social Ethics at Holy Cross; Adjunct Associate Professor of Medicine, University of Massachusetts Medical School.

This article is adapted from a presentation made at the 1984 Annual Meeting of the Connecticut Hospital Association, New Haven, CT.

administrators, hospitals, and for physicians? It means that we can no longer continue down the path we have been following, i.e., if there is a life at stake, "hang the cost." We simply can no longer devote an ever greater proportion of our assets to one segment of our social living.

Examine what has happened over the past three decades. In 1950 we devoted 4.5% of the Gross National Product to health care; in 1984, it is over 10.8%. These statistics alone are a challenge to Dr. Leaf's thesis that no other consideration can intervene in that hallowed contract between a patient and a physician. If that Norman Rockwell portrait of the patient-physician relationship were ever true, that era has ended. For it assumed several propositions that no longer prevail: a private physician-private patient; the patient assumes responsibility for his decision; the patient personally pays for whatever treatment is provided; and the expenses are within the individual's means. Prices in today's acute care hospitals are far beyond the wildest dreams of the 1950's physician. At the major children's hospitals in this country, the per diem charges in a neonatal intensive care unit run between $2,000-$3,000 a day. The costs have escalated dramatically for a combination of factors: the increased use of highly sophisticated and increasingly expensive technology, a wealthy and well-insured populace, and a society growing even more aged and ever mounting expectations on what medicine can do.

With Blue Cross blunting the jolt of out of pocket expenses, nothing is considered too good for Granny. Granny herself, as part of the fastest growing segment of our society, is proving an exacerbation of the problem. Older people constitute an ever larger proportion of chronic care cases.

One of the pressing problems of our times is: Is it ever ethically appropriate to put constraints and limits on the amount of money expended on the aged? At a recent Hastings Center conference, Robert Veatch of the Kennedy Institute for Ethics presented what was considered an unpopular, but nonetheless courageous, standard. It is not discrimination in the negative sense of unfair, but in the positive sense of decision-making based on prudent choice to say, "Yes, you have had 90 good years of life, and so we are not going to continue to put the same amount of resources into your care as that of a newborn or a 20- or 40-year-old." The unfairness, in an age of limited resources, would be to allocate blind to the fact that the octogenarian or centenarian has already had decades of benefit from the common assets and that these now, if scarce, should be distributed in such a way to give others the same opportunities.

Veatch's speech was the first moral defense of that proposition I heard articulated by a philosopher. But, on reflection, it is no more than what the old Irish or Italian grandmother would have stated in plainer, but no less forceful fashion, when saying, "I've lived my life, now you go and live yours."

The constraints are not only being proposed for the aged. Arizona, a very conservative state, is now in the throes of an enormously bitter battle between medicine and the business community. The four largest employers in that state paid out $50 million last year in health care costs and they say, "That's enough. We cannot stay competitive and continue to pay that kind of expenditure." And so they have proposed a referendum, which will appear on the November ballot, to set up a new three-person commission in that state to regulate physician fees and hospital costs.

The corporation that has most clearly articulated a concern with health care costs is Chrysler. In 1981, Lee Iaccoca, that great regenerator of modern American business, decided to take a look at what was happening as Chrysler was facing bankruptcy. He asked Joe Califano, the quintessential liberal, former Secretary of Health and Human Services, and newly-appointed director of Chrysler, to do the investigating. Those of you who read Califano's *The New York Times* op-ed column saw the transformation in Califano's approach as he realized what was occurring in the American health care scene.

Chrysler learned that its biggest single supplier was not U.S. Steel, but the Blues, and that the cost of health care coverage for every presently employed worker, for himself, his dependents, the unemployed and the retirees, was $5,700 per person. At the same time, Mitsubishi was paying $815. It was costing Chrysler somewhat in excess of $600 per car to pay for the health care of its workers. That is, more than 10% of the cost of the automobile, the product produced, went to health care. Chrysler said, "Given those constraints, we cannot remain competitive in the international market."

And what were they getting for their dollar? If they were getting wonderful health care, you might say it was worth the cost. They discovered that in the state of Michigan they were paying $4 million a year for podiatrists. Now I've never seen a podiatrist, but I gather a podiatrist has never seen a normal foot.

A study of hospital admissions indicated that in 80% of the maternity cases analyzed there was one or more days of unnecessary hospitalization. In fact, one quarter of all the hospital days for maternity care were considered unnecessary.

These figures, though, pale when compared with the increased usage of psychiatric services. In 1973 Chrysler workers had 34,000 visits to psychiatrist. Just five years later that figure had jumped over fourfold to 160,000. In Califano's words, "Either we have the largest number of psychotics in the work force, or the most tranquil work force in America. And we don't know which."

He then continued, "This much is certainly true: the psychiatrists are flocking into southern Michigan the way prospectors went west for the gold rush. But they are 'pikers,' " he said "compared with opthalmologists who charge $2,000 for a 20-minute procedure."

Chrysler also looked at some of the more common, less esoteric ailments like lower back pain. I have them, you've got them and so, apparently, do thousands of Chrysler employees. Of those admitted to hospitals for the problem, 2/3 were found to be inappropriately hospitalized. There was an obvious conclusion to Chrysler's investigation. We have got to change the system.

One thing we know, the macroallocation question is not going to be wished away. It does no good to say, "Stop the MX missiles, put the money into health care." The dramatic shift from 4.5% to 10.8% of the Gross National Product – that dramatic shift came from one segment of our society – the defense dollar. When John F. Kennedy became president, we spent 52% of the federal budget on defense. When Ronald Reagan took over the presidency that figure was only 29%. Whether you agree with the MX missiles, Stealth bomber or the "Star Wars" defense, the fact is that this country is committed to strengthening its defense capabilities. The funds for that build up are going to come from one segment of our society – social services.

To propose that we put more money into health care, as the AMA is doing, is myopic. What is called for are microallocation shifts. We are faced with a hard problem, because now the "enemy" of medicine is simply other physicians – those interested in dialysis, the transplant physicians who want to expand, those seeking funds for their own sub-speciality.

If you watched this morning's CBS Morning News, you saw a woman, a recipient of a heart transplant, who is suing the Blues because as she said, "I paid my insurance, and they should give me what I expect, full health care coverage." This statement is made despite a clear restriction in her Blue Cross contract excluding so-called "experimental procedures." And the price of such procedures is going up. Heart transplants are $100,000. Liver transplants cost $240,000 per procedure. Dialysis entitlements ran to $2.1 billion dollars a year. Who is the "enemy" in these cases?

The AMA claims it is not up to physicians to set guidelines, and that may very well be true. But if the physicians, who surely have more insight into this problem than any other segment of the society, abdicate their responsibility, these decisions can and will be made by others. The bureaucrats, courts, or the presidents of the corporations will fill the breach. Donald R. Melville, the president of the Norton Company, a Fortune 500 company located in Worcester, Massachusetts, has stated, "It is more important for us to give a basic level of service to all people than to divert our limited resources toward a few spectacular surgical cases." To achieve that goal, his company is going to the preferred provider route. If you want more extensive coverage, or an alternative health plan, then says Norton Company, "You can pay for it."

Last week at a conference I attended at a Boston hospital for administrators and medical staffs the president of the hospital said, "All that you have been saying is true, but health care dollars will not be cut. Congress will not sit by idle while people die, and the manufacturing community will not sit by without adequate insurance coverage for its workers. The unions are strong and they will demand more than basic coverage in their contracts." This was a community hospital in which all the doctors were fee-for-service physicians. During lunch I asked that president, "Tell me, in your role as a business man, how do you provide insurance coverage for your workers?"

"You know," he said, "it is very interesting. The Blues came in last month with a 25% increase in their rates, and we cannot afford that. So we are now going to go to the HMOs. In fact, you probably saw Harvard Community Health Plan and Tufts recruiting new members when you entered the lobby of the hospital. The real difficulty with this shift is that since all of our physicians are private fee-for-service doctors, our employees will no longer be able to enter this hospital but must go to one of our competitors down the street. I then looked at him and said, "You now have met the enemy."

None of us, including hospital administrators, can be indifferent to costs. A rational resolution of the issue precludes the continual pressures of special interest groups pleading their cause for additional funding before the Congress or, worse still, allocation based on emotional media pitches for a dying child. The Jamie Fiske syndrome might work in an individual case or two, but it is not the way to formulate public policy. Furthermore, though President Reagan himself might make an Air Force plane available to fly in a kidney for the child of a White House carpenter, he is unwilling to provide the funding for the operation or the continuing medical costs for such a procedure.

And what of the needs of the child who cannot attract headlines? How do we provide adequate care for them? One proposal is to use a market mechanism. Allow price to determine allocation. If we adopt that route, we will soon witness Homana, the Hospital Corporation of America, or other proprietary institutions develop in the suburbs and skim off all the profitable cases. As for the poor, their plight is best summed up in two exams I recently received in business ethics. "A new ethic of survival of the fittest, that is, no Medicare, would survive and that people would provide for their own health care needs."

That proposal was more than matched by the student who wrote of the unemployed and totally destitute: "Let them perish. Those who perish would not be equal to the social benefit to those who have provided for their health care costs because the money saved (on Medicare payments) would benefit collective society, other than those who are not contributors to society." Do we really want to live in a society of latter day Herbert Spencers?

To avoid such choices, some propose allocating by lottery. Reflecting on that proposal in a recent *New York Times* essay, Dr. Willard Gaylin of the Hastings Center wrote, "If I learned that there was a choice between me and my six-year-old grandson for one available life-saving machine, and I learned that it had been awarded to me by lot, as the first act of my restored life, I would find the physician who made that selection and throttle him."

A more popular, and at first glance acceptable, resolution would be to allocate on the basis of need. The worst off would receive the most. On reflection, though, such a scheme is fraught with problems. As Zook and Moore note in their *New England Journal* essay on "High Cost Users of Medical Care," vast resources may be spent where the potential benefit is very low. A further problem is that a relatively small percentage of the patients, 15%, consume 50% of the costs. Most of these are chronically or terminally ill.

Does it really make sense to spend 25% of our health care dollar on the last three months of life? Is it true quality care when, as we read in the March issue of *Harpers* on "The Slow and Costly Dying of Mrs. K.," an elderly patient is admitted to a prestigious Upper East Side Manhattan hospital and placed in the ICU. On the fifth day she is slipping closer and closer to death. Her lungs begin to fail; she is put on a respirator; two days later she needs a tracheotomy. Finally, on the 25th day, she suffers cardiac arrest. CPR is instituted; it doesn't work. She dies. The bottom line is that after 25 days of what the physician author describes as "halfway technology," technology which can prevent dying, but not restore life, the patient dies. Her hospital bill alone is $47,000.

The counterpoint to that story is found in a letter section of the April 26 *New England Journal* where a woman psychiatrist writes:

> My sister just died of cancer of the head and neck. She died in a hospice. How many physicians know what death is like in a hospice? Virginia received chemotherapy and radiation without benefit. It was obvious she was starving to death when she left the hospital to enter the hospice. This was a cheerful place, with a large bright room, comfortable beds. There were no monitors, no tubes, no odors, there was a little pain. The contrast between this and death in a hospital in an intensive care unit is obvious. Survivors feel good about the hospice experience because the dignity of their loved ones was respected to the end.

The paradox is that Virginia had to leave a highly staffed acute care institution for a "low tech" hospice in order to improve the quality of care during the final stages of her life, an irony brought about by the fact that many physicians have either forgotten or are unable to deal with a dying patient.

Is it possible to serve both the patient and be concerned with costs? You might find it profitable to read a new book by Aaron and Schwartz entitled: *The Painful Prescription: Rationing Health Care* which describes the British experience of health care delivery, an experience the authors concede is markedly different from our own, but one from which we might well profit. Their text shows that good quality health care can be delivered with less than half the financial resources we provide.

Resolution on Bioethics Committees in Hospitals

At the meeting of the House of Delegates of the Connecticut State Medical Society held on November 15, 1984, it was voted to approve the following resolution on "Bioethics Committees in Hospitals" and send a copy to all Chiefs of Staffs and Chief Executive Officers of Connecticut hospitals. This resolution was previously introduced by the Connecticut Delegation at the AMA Meeting in June, 1984 and was adopted by the AMA at that time. For those hospitals that do not have Bioethics Committees, CSMS recommends that the resolution be implemented:

RESOLVED: That the CSMS adopt the policy that each hospital medical staff form a Bioethics Committee with locally determined guidelines regarding composition, definition of roles, responsibility and authority; and be it further

RESOLVED: That the CSMS adopt the policy that such a committee be available for consultation in those medical illnesses presenting clinical problems complicated by bioethical issues and that a committee be voluntary, educational and advisory in nature so as not to interfere with the primary responsibility of the physician to his/her patient; and be it further

RESOLVED: That this action be communicated to Chiefs of Staffs and Chief Executive Officers of hospitals.

And it can work in this country as well. Daniel Singer's article on "Rationing Intensive Care: Physician Response to a Resource Shortage" in the November 10 *New England Journal* describes what happened when, in 1981 because of a nursing shortage, the Massachusetts General Hospital had to close down 10 of its 18 ICU beds. The physicians reported no increase in mortality, no patients transferred because the hospital could not handle their problems, no shifting of terminally ill patients and no apparent decrease in the quality of care the Massachusetts General provided for its patients. There was, however, an enormous reduction in the utilization of extremely expensive high technology resources. This study shows that physicians, when required, can and do consider cost and resources in their treatment decisions.

Aaron and Schwartz not only note the increasing financial costs of health care treatment, they explain the costs in suffering and emotional drain on patients and families associated with our new-found technological ability to extend life and the concomitant difficulty of stopping treatment once begun. The result is that treatment, designed in theory to benefit the patient, often reduces the quality of the dying patient's life. All of this raises the question, is the reduction in treatment for the terminally ill patient necessarily a reduction in the quality of care for that patient?

Physicians in this country have already begun to realize that aggressive treatment of many terminally ill patients is often pointless. In an important and timely article in the April 12 *New England Journal* some ten physicians from among the nation's most prestigious medical centers provided "Physician Guidelines for Care of the Hopelessly Ill." Those guidelines formulated from years of clinical experience by these senior and seasoned physicians, set parameters and constraints on the medical indications for treatment.

These physicians are also aware of other pressures which contribute to the increased costs of health care in this country such as the demand from families to "do everything," fear of malpractice suits, or threats of court intervention. Yet, none of these absolve medicine from its responsibility to make professional judgments on the appropriate care of their patients. Surely the hospitals and physicians in the State of Connecticut need not call upon the governor or petition the courts to devise a well structured and workable policy on DNR orders.

One way to address these problems, which has evolved over the past few years—a way which spreads the responsibility for the formulation of social policy far wider than physicians alone—is the establishment of a so-called "Institutional Ethics Committee." These broadly based groups of health care providers and the general public, designed in response to the heavy-handed bureaucratic reaction by the Department of Health and Human Services to the Bloomington Baby Doe case and to the fear generated by the first-degree murder indictment of the two California physicians for the withdrawal of an IV feeding line from a permanently comatose patient, are a way for the community to address and begin to resolve some of these pressing social value issues.

This much is clear: During the past two decades we have had the financial resources which allowed us the luxury of the illusion that we could achieve salvation through science and immortality through medicine. And the yet more devastating illusion that cost was never to be a consideration. That era has ended. And its end is not unreasonable. It is not unfair, and it is not unacceptable.

For it produced a system that allowed us to resuscitate a terminally ill cancer patient 52 times despite his plaintive pleas "to be let go." It led us to transfer end-stage liver patients to the ICU. And it permitted us to keep brain-dead patients "alive" on respirators for months in the "hope of a miracle."

Such a system was bad law, was bad medicine, and it was bad health care. In fact, it was not health care at all.

It was an abuse—an abuse of technology, an abuse of the patient and above all an abuse of the society and its resources, resources given to us by God, not for useless struggles against the inevitable, but for the upbuilding of the entire community and the common good.

It was intelligence and the application of reason to the problem at hand that produced the technology, the longevity, and the wealth that resulted in the legal, ethical and moral dilemmas we now face in medicine. It will be intelligence—tempered, one hopes, with compassion—which will allow us to begin to approach these clear and painful choices, now confronting us.

A Case Study in the Abdication of Professional Responsibility

Purple Dots and Red Circles

JOHN J. PARIS, S.J.

Let me share with you what happens if medicine abandons such responsibility. Those of you who have followed the on-going saga of medical care delivery in the state of New York have seen that the latest issue is DNR (Do Not Resuscitate) orders. It has become a crisis this spring, but its prelude occurred three years ago.

At that time the Deputy Attorney General, who serves as the Special Prosecutor for Medicaid Fraud, began receiving reports from the LaGuardia Hospital in Queens that there were suspicious practices occurring at that institution. He began an investigation and found that at LaGuardia some patients for whom there was no confirmed diagnosis were not being resuscitated, and the decision not to resuscitate was being made by medical students.

During an early phase of the Attorney General's investigation, I attended a meeting of the Hospital Association of New York State health care attorneys at which one prominent attorney told the audience of several hundred lawyers, "I want to give you some advice. Now I know that Fr. Paris is going to follow me, and I know he is going to tell you that the advice I am about to give is unethical and contrary to the best interests of patients. He is probably correct. However, as a hospital attorney, I recommend that you tell your physicians: never write a DNR order. Never write "Do Not Resuscitate" in a patient's chart, because, if you do and the patient dies, and the family subsequently wants to sue, that order can be used as evidence that you withheld a treatment that might have saved the patient's life."

When I spoke to that group, I told them that the previous speaker's comments were correct. I believe such a course of action would be unethical and certainly would not be in the best interests of the patient. Furthermore, I believe such advice is foolish. The best possible defense one would have for his or her behavior is a well-documented record on what has been done and what the medical justifications, patient consent or family consent for it were.

Further, I reminded the attorneys present that as far back as 1974, The Report of the National Conference of the American Heart Association had made it clear that:

> The purpose of cardiopulmonary resuscitation is the prevention of sudden, unexpected death. Cardiopulmonary resuscitation is not indicated in certain situations, such as in cases of terminal irreversible illness where death is not unexpected or where prolonged cardiac arrest dictates the futility of resuscitation efforts. Resuscitation in these circumstances may represent a positive violation of an individual's right to die with dignity. When CPR is considered to be contraindicated for hospital patients, it is appropriate to indicate this in the patient's progress notes. It also is appropriate to indicate this on the physician's order sheet for the benefit of nurses and other personnel who may be called upon to initiate or participate in cardiopulmonary resuscitation.

That advice, published in *JAMA* in 1974 had been updated and reprinted just a year before our March 1981 meeting.

My words, though, fell on deaf ears. The result is what is now known in New York as "The Purple Dot Affair," "The Blackboard Bungle," and "The Red Circle Death."

On March 30 of this year, I gave a talk to the Ethics Committee of the New York Hospital/Cornell Medical Center. The first question asked was: "Is it legal to write a DNR order?" Note that the question was not: "Is it ever medically appropriate or in the patient's best interest to write a DNR order?" I replied, "Not only is it legal to write such an order, such an order is standard practice in thousands of institutions throughout the country, and that practice is in conformity with the standard proposed by the National Conference of the American Heart Association." Furthermore, I informed them that as the expert witness for the Special Grand Jury convened to investigate the DNR situation in New York State, I could safely assure them that the Grand Jury's Report would insist that any order had to be in writing, and that if it were not the institution itself would be in trouble.

It is rare that one sees his predictions confirmed so quickly. The very next morning there was a front page story in *The New York Times* on the Special Grand Jury's Report of its investigation into the practices at LaGuardia Hospital. Along with the details of how decisions were being made at that institution was the revelation that, on the advice of hospital lawyers, LaGuardia Hospital had adopted a policy forbidding the writing of a DNR order. The physicians, confronted with that policy and aware that there were some patients for whom a DNR would be appropriate, sought a way around the policy, a way designed in the words of the Grand Jury Report, "In order to avoid legal responsibility for such decisions, and for no other reasons." The method chosen, one designed by the Chief of Surgery, was to attach an adhesive backed "Purple Dot" to the "Kardex" file of those orally designated by the physician, as "No Code." The genius of the Chief of Surgery's suggestion was two-fold: the card files were the sole responsibility of the nursing staff and thus the "Purple Dot" could not be attributed either to the physician who gave the order or to the one who carried it out. Even more important, the cards were routinely discarded after the patient died, and so there would be no record of the decision after its implementation.

Where did they obtain these little purple dots? The hospital gift shop! Now, when you visit Grannie, you can stop off at the gift shop to get her a farewell present. As Ogden Nash might have put it: "I have never seen a purple dot, I never hope to see one. But if I do, I'd rather see than be one."

One might be tempted to say, "LaGuardia is a small, unsophisticated place, but surely the major institutions behave in a different fashion." The day after the Grand Jury Report was issued the front page of *The New York Post* exposed what was occurring in another hospital in the City of New York. One hospital, for example, had a large blackboard in the physicians' lounge on which was written the names of all the patients with a code letter (A, B, C, or D) beside it. A's, B's, and C's would be resuscitated, D's would not. When the patient died, the blackboard would be erased. The hospital? Memorial Sloan-Kettering, one of the world's most prestigious cancer research centers. Asked why they did this, the physician-in-charge said, "Oh, you have to understand, patients' conditions change so rapidly that you cannot write a DNR order in ink."

What, then, do you think was the response of the New York hospitals to this phenomenon? Did they say: "We understand what cardiopulmonary resuscitation is. We understand the national standard that states that CPR is appropriate in cases of sudden, unexpected death, but not appropriate when death is the anticipated outcome of a terminal illness. We understand that CPR ought not be applied in such cases. We understand that it is appropriate to write an order to that effect in the patient's chart. We understand that in acute care facilities with multiple nurses and physicians that it is necessary to have a clear communication policy on these decisions."

No, the New York hospitals did not respond in that fashion. Rather the very next day *The New York Post* had the following headline: "Hospitals Ask Governor Cuomo to rule on the 'Doomsday' Blackboard." The Greater New York Hospital Association joined in the outcry on the "Blackboard of Doom" at Memorial Sloan-Kettering and called upon the Governor to "issue rules on Do Not Resuscitate Orders." In the words of Stefanie Steel, a spokesperson for the Greater New York Hospital Association: "We want some guidelines, and we'll take them in whatever form we can get them." Here is the Hospital Association of Greater New York saying, "Mario Cuomo, you tell us what to write on DNR orders. You decide what is appropriate. You give us the formula, and we'll do whatever you want." This is a group that tells us they do not want bureaucrats deciding how to practice medicine; this is the group that tells officials they don't want the government telling them what to do. Here they have a policy, one clearly delineated for the last ten years, and what do they do? They cry, "Governor Cuomo, tell us what to do."

And it gets worse. Last week the New York press had a story about an 87-year-old grandmother who stopped breathing and was not resuscitated. It turns out there she was in New York Hospital/Cornell Medical Center for a respiratory problem. As the story is related by the family, she had a well-diagnosed non-life-threatening ailment that was in control, and she was about to be discharged. Her grandson, a Boston physician, visits her, and believes she is asleep. He notices that she is not breathing so he immediately begins mouth-to-mouth resuscitation. He calls a nurse, the code team rushes in, and he is told to leave the room, and they do nothing. He comes back in and says, "Why aren't you resuscitating my grandmother?" And they reply, "Oh, she's a DNR. Look, see the red circle around her room number? That's the code we use for Do Not Resuscitate." And the woman dies.

I propose that "Purple Dots" and "Red Circles" are not the way to go. And calling on the Governor of New York to give you guidelines on DNR orders is not the way to go either. We do indeed face dilemmas in health care delivery, but there is a long tradition in medicine, and there is a good deal of reflection and analysis that has occurred that can be used before we do what the New York Hospital Association did, that is, abandon the practice of medicine to the bureaucrats, or worse to the courts with the expectation that somehow that action will absolve us of the responsibility of decision making.

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"Baby Doe" Draft Regulations Published

Once again tackling the issue of when to withhold treatment—and how to intervene when treatment is inappropriately withheld—the Department of Health and Human Services (HHS) in December published draft "Baby Doe" regulations to implement the new Child Abuse Prevention and Treatment Act amendments passed by Congress earlier this year.

The proposed regulations more narrowly define instances when treatment should be withheld than the broader language of the Act. According to the proposed regulations, care should be withheld only when:

- the infant is chronically and irreversibly comatose.
- treatment would not correct all of the infant's life-threatening conditions. (These are conditions that would significantly increase the "risk of the onset of complications that may threaten the life of the infant," HHS said.)
- treatment would merely prolong dying. (These are situations when "death is imminent," according to HHS, and would not include a more lingering death by diseases such as Tay-Sachs.)
- treatment would be virtually futile and inhumane, meaning that treatment is highly unlikely to prevent imminent death.

Additionally, the proposed regulations "strongly recommend" the establishment of Infant Care Review Committee (ICRCS) in hospitals that care for infants, especially those with tertiary level neonatal care units. The committees could educate hospital personnel, recommend institutional policies, and offer counsel and review in Baby Doe cases, HHS stated.

The comment period will end February 8. Final regulations will be issued before March and states will have until October 9, 1985, to comply. Funding for the program, for such as medical consultations, will come from state child abuse grants.

The American Medical Association, which has successfully fought earlier Baby Doe regulations in the courts, immediately announced that it will use the public comment period to voice its continuing concerns regarding the amendments and the regulations.

"The Association continues to believe that the public does not agree with the goal of this legislation—which is to have government intrude into the right and responsibility of a mother and father to consult with physicians, clergy and other advisors and make a decision about the nature of their child's treatment," AMA Executive Vice President James H. Sammons, M.D. said. "The Association will continue to help protect the rights of families and to challenge the implementation of this legislation when it violates those rights."

Under the proposed regulations, Baby Doe cases will be treated like any other case of child abuse, with intervention by state authorities to prevent medical neglect. The state can pursue any legal remedy to prevent withholding of medically indicated treatment. Any investigation, however, must include coordination and consultation with a designated member of the hospital.

The proposed regulations are tied to the child abuse funds that the federal government dispenses to states each year; thus, any state willing to give up the funding would not be required to comply with the Baby Doe regulations. Last year, states received a total of $16.2 million—an average of $324,000 per state—to administer these child abuse programs.

The proposed regulations are different from the "section 504" regulations issued last year and twice rejected by the courts. Whereas the earlier regulations were based on laws prohibiting discrimination of the handicapped, the new regulations are based on laws prohibiting child abuse. There are important philosophical differences: the earlier "504" regulations insisted that handicapped children be provided the same care as non-handicapped children; the new regulations say that handicapped children be provided the best care for their certain circumstances, and admit that there are circumstances when no care at all is the best course.

The earlier "504" regulations demanded federal intervention, with hotlines and investigative squads. The proposed regulations leave all intervention up to state authorities (some state child abuse programs already have hotlines and conduct investigations). The exact implementation of the law will depend on procedures set up by each state.

In an unrelated action, HHS asked for comments on guidelines that establishment of Infant Care Review Committees (ICRs) in hospitals that care for infants,

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Prepared by the Washington, D.C.
Office of the American Medical Association

especially those with tertiary level neonatal care units. Although the committees are not required, they could educate hospital personnel, recommend institutional policies, and offer counsel and review in Baby Doe cases, HHS stated.

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HHS Savings In Medicare

The Department of Health and Human Services expects to save an estimated $3.7 billion over the next five years as a result of actions taken in 1984 on recommendations of the Department's Inspector General.

The savings represent a $58 return on each dollar spent by the IG's office.

Detailed in the IG's year-end report to Congress, most of the $3.7 billion is estimated future savings from program changes legislated or implemented at the recommendation of the IG. The remainder is due to recoveries and fines imposed on program beneficiaries, providers and contractors.

The bulk of the savings—which are 166% higher than those of the previous year—occur as a result of legislative changes in the Medicare and Medicaid programs, particularly those affecting payments to clinical laboratories. They also include recoveries of inappropriate or fraudulent charges and fines for fraudulent or abusive behavior.

Some 900 individuals were prosecuted for attempting to defraud HHS programs and another 400 convictions were obtained by state Medicaid fraud control units. Of these, 327 health providers or suppliers were "kicked out" of Medicare and Medicaid and $7.5 million was recovered in settlements under the Civil Monetary Penalties Act.

The report also recommends other program changes the IG contends could result in further savings. These include a mandatory second opinion program and a plan that would round down to the next lowest dollar any odd penny claims from patients or their doctors for Medicare-covered physician services.

* * * *

Capital Costs Considered Under PPS

Administration officials indicated in December that the fiscal 1986 budget may bring capital costs into Medicare's prospective pricing plan.

When it moved Medicare from cost-based payments to a prospective pricing plan based on diagnosis-related groups (DRGs), Congress left capital under the old cost-based system but required that it be brought into the DRG system by October 1, 1986. A report on how the Department of Health and Human Services proposed to do this was due to Congress last November, but the report is late.

The capital proposal, which may become a part of the budget proposal, reportedly is likely to add about 7% to each of the 468 DRGs to cover Medicare's share of hospitals' capital expenditures. Although existing capital spending commitments probably will not be exempted from the plan, the provision may include a transitional plan to alleviate the impact of the proposal on hospitals in the middle of expensive building or renovation.

Meanwhile, Sens. David Durenberger (R-MN) Chairman of the Senate Finance Committee and Robert Dole (R-KS), the new Senate Majority Leader, have written HHS Secretary Margaret Heckler to ask why the capital report has not been issued.

Durenberger also has proposed a block grant to replace Medicare's pass-through of the direct costs of medical education. The Administration supports this approach and is said to be working with Durenberger to design a single block grant to include the Medicare payment for medical education along with the Public Health Service's health professions education assistance program. This proposal also may be part of the 1986 budget proposal.

* * * *

Durenberger Said To Doubt DRGs For Physicians

Sen. David Durenberger (R-MN), who heads the Senate Finance Health Subcommittee, reportedly is having doubts about plans to include physicians in a prospective pricing scheme based on diagnosis.

Durenberger, whose influence on health policy is expected to expand as a result of changes in Senate Republican leadership, had previously said he favored the inclusion of a physician payment in each of the hospital DRGs.

Recently, however, Durenberger has said that while he still thinks physicians will have to be brought into a prospective system, he is not certain that DRGs are the best way to do this. That view has also been reiterated by Durenberger aide Chip Kahn.

Addressing a recent meeting of the American Health Planning Association and the National Health Lawyers Association, Kahn said he thinks rushing into a DRG for physicians is a little frightening. He suggested that research on a physician DRG has had mixed results and expressed concern that a doctor DRG could change the physician-patient relationship. Senate staff will be very cautious on the issue of physician reimbursement changes and on inclusion of capital expenditures in DRGs, he predicted.

BEHIND THE FACE OF HYPERTENSION

New evidence for central control

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VA To Backstop Military Medicine In Event Of War

The Veterans Administration, the traditional provider of care to veterans, now has a new mission: to backup the Department of Defense in the event of a war or national emergency.

Results of a new survey show that the VA can promise the military 19,000 beds within 72 hours and 31,000 beds within 30-45 days.

Service-connected veterans still will be first priority for the VA system. Non-service-connected veterans, however, will be transferred to private hospitals to make room for incoming servicemen.

The VA would receive patients as the DoD's medical facilities become saturated. When the VA's beds are filled, military casualties will be sent to backup civilian hospitals. In practice, the very seriously wounded patients—those with spinal cord injuries, burns, and blindness, for instance—would be shipped immediately to VA facilities for long-term care.

The system, part of a larger VA-DoD sharing plan enacted into law in 1982, was prompted by increasing concern over the cost of medical care in the nation's federal hospitals. The law, PL 97-174, upgrades the priority for VA care of the active duty casualty and gives the VA the flexibility it needs to enter into long-range plans with DoD.

The system depends on 71 primary receiving hospitals to care for the first wave of casualties. The hospitals were chosen because they are near the point of military debarkation, contain at least 150 beds, and are within 50 miles of a VA or DoD coordinating center.

Secondary receiving hospitals, although less well-equipped for a major influx of casualties, will share resources and accept patients from the primary receiving hospitals. Third tier installation support centers will provide health care support to medical personnel deployed out in the field.

All 28 VA medical districts have established contingency planning task forces that have been cleared by the district and regional levels and are now awaiting final review at the national headquarters in Washington.

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America's Proposed National Disaster Medical System

India's recent gas leak sent more than 10,000 people to hospital emergency rooms, but hundreds of victims were treated on the lawns outside the city's hospitals because all the beds were full.

In the Mexico City gas explosion, burn patients crowded into hospital hallways; churches and a subway station became first aid centers. Blood, plasma, and medical supplies ran dangerously short in the seven hospitals treating the city's 3,000 victims.

How could the United States respond to similar disasters?

Trained medical assistance teams could rush to the scene to perform field rescue and first aid. The most critically injured would receive surgery at the disaster scene; the less seriously injured would receive first aid until ready for evacuation. As many as 100,000 patients could be distributed to hospitals awaiting them with supplies and personnel.

The planned National Disaster Medical System is being developed in response to President Reagan's 1981 mandate to improve emergency preparedness. Modeled after a Department of Defense plan to handle excess casualties in military conflicts, the NDMS is designed to respond to a wide range of emergency situations. Two pilot disaster units are already operating; others will form within the next three years.

NDMS will provide nationwide medical help when local, state, and regional facilities are overwhelmed by a serious disaster, Thomas P. Reuthershan of the Department of Health and Human Services said recently. It is not designed to replace local disaster relief teams but will supplement local efforts with a broad-based network of national support.

The system would be triggered by three situations: a Presidential declaration of a major disaster, a state request for help, or a major war or national security emergency.

The US now has the lowest number of available hospital beds in history. NDMS could support only a conventional, non-nuclear war in which the US is not under direct attack, authorities note; a nuclear war would overwhelm the capabilities of the NDMS system.

No single community can be fully prepared for war or a catastrophic event, said Reuthershan. Although all cities and states are well-stocked with medical supplies, it is virtually impossible to anticipate a sudden surge of injuries.

The system is a showcase of private-sector volunteerism. It would require no new hospital construction. Nor would it demand the purchase of extra equipment, or training of special staff.

Although modeled on Washington, DC, the actual implementation of the system is decentralized in 71 communities across the country. A national center—composed of representatives of the Department of Health and Human Services, Department of Defense, Federal Emergency Management Agency, the Red Cross, and other federal and private health agencies—would manage the federal response to a disaster.

Medical teams would be trained as volunteers, although compensated for their work during an actual emergency. Hospitals of 100 or more beds would also enroll, volunteering to participate in training and exercise programs but receiving compensation for each patient. Medical supplies would be provided by preexisting Packaged Disaster Hospitals; patients would be evacuated on Air Force helicopters, or on commercial jets, trains, and buses.

* * * *

Congress' OTA Looks At ICUs

Because intensive care unit (ICU) patients are "revenue losers" under the diagnosis-related-group (DRG) system, hospitals may feel pressure to change the way they offer ICU care, a new Congressional office of Technology Assessment study concludes.

"The new incentives of the DRG payment system will be imposed in many hospitals in which the costs of ICU care had previously been a relatively minor concern," according to a report of the study.

Hospitals may decide to reject ICU cases, transfer them to other facilities or accept them at a loss. They may ration ICU care to only certain favorable-outcome cases, or impose cost-controls on ICU physicians, it states.

ICU decision-making could become even more difficult due to the potential financial conflict between patients, physicians, and hospitals, the report warns.

ICU hospitalization days are 3-3.5 times more costly than non-ICU days. In addition, ICU patients have longer hospital stays than non-ICU patients. It has been estimated that 15-20% of all patients are cared for in an intensive or coronary care unit at some point during their hospital stay.

A very small portion of the ICU patient population consumes a substantial portion of total ICU resources. ICU care appears to be well-invested in cases of acute, reversible disease such as a drug overdose or major trauma; ICU care may be less cost-effective in severe, debilitating chronic illnesses such as cancer or cirrhosis, the report states.

Until recently, ICU care has not been subject to the same restraints as intermediate or general care. For example, 1980 Medicare rules tightened the payment limits on routine bed costs but not on ICU bed costs. Furthermore, utilization review boards generally do not consider the appropriate level of care within a hospital.

ICU physicians feel little incentive to keep the unit empty or restrict technical procedures. The current system of physician payment—based on a usual, customary, and reasonable charge system—has rewarded physicians who provide abundant ICU services. Additionally, there are non-financial reasons to provide ICU care: it is difficult to predict an ICU patient's chances of survival; ICU patients are often mentally incompetent; and the threat of lawsuit encourages continuation, rather than withdrawal, of care.

OTA predicts that the new payment environment may change hospitals' attitudes about the appropriateness and extent of ICU care. ICU patients are expensive: they often have multiple diagnoses and suffer severe health problems that do not fit neatly into DRG disease "entities." In one study, ICU patients had an average of four major diagnoses; high-cost nonsurvivors had six diagnoses.

The DRG classification scheme may be poorly suited to describing ICU patients, it says. For example, severity of an illness is not taken into consideration. Gastrointestinal bleeding in patients with cirrhosis is associated with long ICU lengths of stay, yet the DRG for cirrhosis has a mean special care length of only 0.6 days.

Nor does the DRG system take into account those ICU patients with a primary surgical diagnosis who suffer major medical complications. For example, hospitals which treat patients with renal failure are reimbursed based on the operating room procedure, not the ICU care needed to sustain non-functioning kidneys.

The DRG payment system does allow additional payments for "outlier" cases, which have long lengths of stay or are unusually expensive, it notes. However, the outlier policy pays hospitals less than the marginal costs of caring for the sickest ICU patients.

Because there is no financial penalty for transferring patients to another hospital, the sickest ICU patients may be moved to tertiary care facilities, it predicts. The hospital which keeps a patient only four days get paid 40% of the DRG total payment; on the other hand, a hospital which must keep the patient until he recovers—or dies—is less likely to recoup its full investment.

If the trend continues, tertiary care hospitals may inherit most ICU cases. They may reject them, accept them at a financial loss, or try to minimize expenses by converting separate ICUs into larger, more centralized, and more general ICUs. They may substitute lower-paid health personnel for nurses and physicians when cases require only routine monitoring. Or there may be new efforts to find cost-saving technologies that will replace expensive ICU labor, according to OTA.

Tertiary care hospitals could become, in effect, large ICUs. They may place cost controls on their ICU physicians, paying them salaries as the major form of renumeration. New incentives, like physician bonuses for reduced costs or decreased lengths of stay, could be proposed.

The report suggests several steps to ease ICU decision-making:

- increase research to pinpoint the predictors of survival in ICU patients with various illnesses,
- evaluate and perhaps modify the current DRG method of payment for ICU cases,
- recognize the current conflict between law and medicine: high malpractice standards vs. limited medical resources,

- better educate physicians about medical ethics and legal obligations,
- create formalized decision-making committees in hospitals to lessen the burden on physicians faced with difficult choices about ICU treatment.

* * * *

NIH Panel Nixes Surgery For Sarcomas

Following the trends towards less destructive cancer therapies, a panel of physicians convened by the National Institutes of Health has recommended that radiation and chemotherapy can replace amputation as the best treatment of sarcomas.

Multiple studies from major medical centers indicate that amputation can be avoided without jeopardizing the lives of these patients, the experts said at an NIH conference.

Amputation has been the traditional mainstay of treatment of adult soft-tissue and oeteogenic sarcomas because of high recurrence rates when only local surgical resections were performed. Yet removal of the limb impairs a patient's function and erodes his self-confidence, the NIH panel said.

During the past 15-20 years, radiation and chemotherapy have become increasingly effective in treating the 4,800 cases of soft-tissue sarcoma and 1,900 cases of osteosarcomas diagnosed each year. Between 30 and 50 cancer centers around the country now are exploring these alternatives to amputation. Amputation and limb-sparing treatments show similar rates of local recurrence of cancer: 0-10% in cases of soft-tissue sarcoma and 10-20% in osteosarcoma. Five year survival rates for the two different treatments also are similar.

For soft tissue sarcoma, the experts recommend:

- use of shrinking fields to limit the highest dose of radiation to the area at greatest risk for tumor persistance,
- saving a 1 cm longitudinal strip of normal tissue along the limb to prevent edema, and
- delivery of doses of 5,500 to 6,500 cGy over 5½ to 7 weeks.

For osteosarcoma, they suggest:

- use of either intra-arterial or intravenous chemotherapy.
- adjuvant treatment to reduce local recurrence, and
- possible use of pre-operative regional chemotherapy to product necrosis in tumors.

There are situations, they point out, when limb-sparing treatment is not appropriate. For example, such treatment should not be used for lesions with little surgical margin or for lesions that involve major vessels and nerves. Limb function, if salvagable, should be at least equal to that of a prosthetic device. For instance, legs should be able to bear weight and hands should be functional.

* * * *

1984 Sees PRO Startups

Over the objections of a leery White House budget office, physicians in 1984 managed to hang on to a pivotal Medicare review role intended to protect the program's coffers as well as its patients.

Government negotiators drove a hard bargain, however, and the new Peer Review Organizations (PROs) that will be performing the reviews have made some formidable commitments that are likely to bring about—or at least hasten—major changes in the way medicine is practiced in the US. Few of the winning contractors have any illusions about their future should they fail to live up to their bargains.

The brainchild of Minnesota Republican Senator David Durenberger, the PROs were established in a 1982 law as a replacement of the predecessor Professional Standards Review Organization program. Federal efforts to get the new PROs up and running didn't start in earnest until February 1984 when bid requests for the two-year PRO contracts were finally issued, however.

The PROs will differ from the old PSROs in several important ways. Their workload has been consolidated so that where there were about 200 PSRO areas, there are only 54 PRO areas. Although PSROs were not precluded from reviewing private patients care, the PROs not only are permitted but are required to conduct private reviews when requested. And perhaps most important, the PROs will be working under performance-based contracts that spell out some very specific goals they are to achieve.

The goals, aimed at curbing potential abuses under Medicare's prospective price controls, include several intended to reduce hospital admissions. The PROs also are directed to assure that quality of care does not deteriorate. In fact, federal officials increased their demands in the quality area after complaints that initial bidding guidelines were deficient in this area.

The bulk of the PRO contract awards (44) went to the old PSROs; a number of other new PROs have PSRO subcontractors. Nine state medical societies (Maryland, Indiana, Missouri, Nebraska, New York, North Carolina, Texas, and Virginia) also won PRO bids. In seven areas, review will be conducted by another state's PRO. Only in Idaho will the review be performed by one of the insurers that administer Medicare for the government.

The bidding outcome was a relief to many observers who thought more of the contracts would go to Medicare intermediaries.

An Antitrust Primer for Physicians

GEOFFREY T. ANDERS, J.D., C.P.A., C.P.B.C., LEIF C. BECK, L.L.B., C.P.B.C.,
BRAFFORD B. BAK AND JOSEPH W. GALLAGHER

Physicians traditionally have not viewed their colleagues, or even nonphysician health providers, as "competitors." That view, however, is not shared by the courts when interpreting antitrust law. Especially today, given the development of alternative delivery systems and the expected doctor surplus, physicians must be extremely leery of possible antitrust violations.

Obeying that injunction may be quite difficult. Physicians generally have little understanding of antitrust law. Worse yet, application of antitrust standards to the professions generally and to medicine in particular is relatively recent. Since antitrust legislation for the most part is quite vague, much of the actual law has been developed by the courts. Thus the guidelines for physicians must be assumed by analogy to decisions affecting other industries—a process which in any particular case may or may not prove valid.

It is clear that as an environment dominated by solo physicians gives way to various combinations of doctors, great care will be needed to avoid overstepping antitrust law boundaries. This article is not intended to be a legal treatise on the subject. It is hoped, however, that the discussion below will highlight areas of concern so that appropriate legal counsel will be sought before action with possible antitrust issues is undertaken.

The Risk and Legal Status

The risk run in violating the federal (and often, though not in Pennsylvania, state) antitrust laws should be well noted.

Certain violations may be prosecuted as criminal violations (although "civil" litigation is much more frequent). Even with non-government plaintiffs the risks are high. Antitrust litigation is the most costly of all suits. We know of a hospital spending $1 million defending a "staff privileges" case. And the hospital won! Losses may be even more costly since damages can be assessed at three times the amount actually proved. Clearly the best alternative is to avoid even questionable activities so that no grounds exist for possible antitrust action.

What activities give rise to antitrust difficulties? Broadly stated the policy of the antitrust laws is to eliminate actions which inhibit business enterprises from having the full opportunity to compete on the basis of price, quality, and service. The primary areas of concern might be attempts to monopolize (including mergers), group boycotts, price fixing, and exclusive dealing contracts.

Attempts to Monopolize

Under federal law it is not illegal to have a monopoly. But it is illegal to attempt to form a monopoly, to conspire to gain a monopoly position, or to use predatory practices to maintain a monopoly position.

A monopoly may be defined as a practice which, due to its share of a particular product or service market, has the power to control price or exclude competitors within its particular geographic market. That power is usually inferred simply due to a practice's size. Thus a practice which provides 60 percent or more of a particular service (including any acceptable substitute services) will often be deemed a monopoly. Since having a monopoly is not itself illegal, but only attempts or conspiracies to gain a monopolistic position, two primary areas of concern for medical practices arise: mergers and exclusive contracts.

In recent years the trend has been to larger and larger group practices. Initially that growth was, for the most part, internal. Solos or small groups would simply add a doctor from outside their community as practice demands grew. With the trend to large practice accelerating, many solos or groups are now contemplating merger with other already existing practices. In such cases it is essential to consider the antitrust implications.

If, as a result of a merger, the new practice attains monopolistic size or competition decreases substantially, an antitrust violation results. While a 60 percent market share generally is viewed as the threshold for a monopoly, the probable effect of substantially reducing competition may result if the market share of the merged practice is much less, perhaps in the area of 30 percent.

Physicians contemplating merger initially must consider whether the merger might be viewed as an unreasonable restraint on competition. The geographic market—the area in which patients may reasonably turn for alternative care—must be defined. Each major service (including medically acceptable alternative services) must be examined to determine whether the merger would result in a monopoly or substantially lessen competition among providers of the service within the geographic market.

While mergers and attempts to monopolize must con-

The authors are the principal consultants of The Health Care Group, Bala Cynwyd, an information service for practicing physicians.

cern practices with both small and large market shares, physicians who already enjoy a monopoly position have other concerns. Monopoly power may not be used either to maintain the position in a market or to compel advantages in the marketplace.

One example of the illicit use of monopoly power comes in the area of exclusive contracts. A practice having a monopoly position which imposes an exclusive contract on a hospital, if the implicit or explicit threat is otherwise not to admit to the hospital, abuses its monopoly power and violates antitrust law. Practices generally may accept an exclusive contract, even a practice with a monopoly position. The point is that physicians may not use monopoly market power to force the grant of exclusive rights. Such an offer must come freely from the other side of the arrangement.

Group Boycotts/Refusals to Deal

Most of the physician-related antitrust litigation has come in the area of "group boycotts," usually resulting from the denial of hospital staff privileges. It is an area requiring extreme care, particularly since hospital staff positions often place physicians in a somewhat unavoidable conflict.

A violation of antitrust law must involve (1) a conspiracy; (2) a refusal to deal, a boycott; and (3) a purpose and (4) effect of freezing out a competitor. The refusal to deal and effect of freezing out a competitor elements are patent since no dispute would otherwise arise. Thus the litigated cases tend to focus on whether or not a conspiracy existed and whether the purpose of denying a physician's application for privileges was motivated by economic reasons.

Conspiracy claims often arise since a hospital medical staff routinely is involved in the credentialing process. If at all possible a physician should voluntarily remove himself from considering a potential competitor at the departmental, committee, or board level.

Usually that alternative is not available, however, so physicians must be extremely careful in their hospital-related roles. The fact of the matter is that "competitors" are involved in passing judgment on an applicant's privileges. Physicians must act carefully so that any involvement clearly shows that the action is within the doctor's role in relation to the hospital and not as a privately practicing physician.

To date courts have been reticent to attribute anti-competitive motives to physicians in the credentialing process, but that is no guarantee for the future. Doctors should be certain that their hospital's privilege considerations procedures insulate against the finding of a conspiracy. Thus the credentialing process should provide for "due process" and the opportunity for fair hearings at each step. Physicians should be certain of religious adherence to this "due process." The department's or chief's recommendation should be only one of many opinions. Physician discussions should be limited to the hospital's interests—ethics, competency, personal qualifications, etc.; no mention of practice economics should be made. Finally the ultimate decision whether or not to grant privileges should be in the hands of the hospital's governing body and without physician-member participation.

The crux of a staff privileges case will usually be the purpose for the denial, that is whether or not the reasons were anti-competitive or not. In the absence of a valid hospital reason, it may be inferred that physicians on staff are only seeking to protect their economics. Proper reasons for staff privilege rejections have included: competency and quality concerns, efficiency in the use of hospital facilities such as the operating room, preeminence of the teaching mission in a teaching hospital, the hospital strategy for competition with other hospitals, the hospital's desire for full time geographic staff and bona fide exclusive contract arrangements.

On the other hand, concerted action among physicians to coerce a hospital not to employ a competing doctor or to grant privileges to an osteopathic (or allopathic) physician simply on that basis is not legitimate. Similarly denial of privileges because of the applicant's participation in an HMO, PPO or other venture competitive with the hospital or its medical staff is not appropriate.

In the future, staff privilege cases promise to become even more complex. Hospitals in some cases are moving to "closed" departments or entire staffs. New staff appointments may be conditioned upon promises to remain "full time, geographic." With the prospective payment system, staff privileges may be revoked if physician's practices are costly to the hospital. The legality of such decisions should turn on the extent to which these policies are independent decisions of nonphysician hospital boards. Physicians should in no event recommend or impose these restrictive rules of their own accord.

Illegal boycotts or refusals to deal may occur in circumstances other than staff privilege matters. Clauses in shopping center leases permitting tenants to veto new tenants have been held illegal. That same result might well occur in a professional office building or campus where practices are guaranteed that no tenant of the same specialty will be permitted without the existing tenant's approval.

Similarly agreements among competing colleagues not to participate in an HMO or other alternative delivery system are illegal boycotts. While each practice independently may decide not to join such an organization, any concerted action may be viewed as an agreement. Doctors must exercise care that such discussions do not arise in medical staff or departmental meetings, since even the appearance of impropriety followed by common action, even if independently determined, could lead a court to conclude that a conspiracy exists.

Price Fixing

It is well known that agreements among competing doctors fixing the fee for services are illegal. What is less well known is the extent to which that prohibition extends.

Any agreement between competitiors that affects price, that is, that interferes with the freedom to make price changes is illegal simply by the facts of the agreement and the effect on price. It does not matter whether the agreement establishes minimum or maximum prices outright, or simply stabilizes prices, establishes a uniform discount policy, or mandates some other basic element of price, such as agreeing to accept assignment or participate in an insurance program.

The law against price fixing holds traps for doctors. For example, if competing physicians decide to form a Preferred Provider Organization (PPO), they may run afoul of antitrust law if fees are uniformly or jointly negotiated with business. Upon deciding that each participating practice would offer a uniform 10 percent discount, for example, a price fixing violation would seem to occur. Such an arrangement might be saved if the PPO permitted individual practices to negotiate charges with subscribers directly or if the PPO was a true joint venture, itself providing the medical services rather than providing them through the constituent doctors' practices.

Other agreements also may fall into the prohibition against price fixing. While the law is not clear, hospital contracts with doctors, such as EKG reading, anesthesia, or radiology exclusive contracts, which require hospital approval of the fees physicians are to charge, may well be illegal. In the one court decision dealing with these arrangements from a price fixing standpoint, the court held that if such agreements have the purpose or effect of fixing prices, a violation would result.

Exclusive Contracts

Recent changes in Medicare billing and reimbursement procedures have prompted hospitals to place physicians on separate billing arrangements for performing in-hospital services, such as cardiac test, pulmonary function, EMG and EEG reading and interpretations, and other services traditionally rendered by hospital based physicians. The change to separate billing has led to a rash of exclusive contracts providing that the hospital will look only to one group for a particular service to its patients and that the group will fulfill all of the hospital's requirements.

Such exclusive arrangements may violate antitrust laws if their procompetitive effects do not outweigh their anticompetitive consequences.

As a general matter the longer the term of the contract, the greater the dollar volume and the larger the market share, the greater likelihood that an antitrust violation results. If a substantial amount of competition in a particular geographic market is foreclosed, the exclusive agreement will not be permitted.

Determining whether the anticompetitive impact exceeds the benefits to competition is not a clear cut matter. While exclusive contracts reduce day to day competition among physicians for patients and referrals, competition is enhanced at the physician level when the contract is up for renewal. Presumably interested doctor groups will compete or bid for such contracts. Furthermore, exclusive contracts may permit hospitals to compete better in their own markets for both patients and physicians.

Physicians entering exclusive contracts should be alert to possible antitrust problems. If a small number of hospitals operate in the area or if the contract term is unduly long, expert antitrust counsel certainly should be sought.

Some aspects of the law concerning exclusive contract arrangements are presently an area of great uncertainty due to a novel approach by the Fifth Circuit Court of Appeals in examining a hospital's exclusive arrangement with the anesthesia department. After considering the arrangement the court determined that an antitrust violation occurred since the effect of the contract was to "tie" the sale of anesthesia services to the patient's purchase of hospital operating room services, which is illegal. Patients could not avail themselves of surgical services in the hospital without being compelled to purchase anesthesia from the particular group holding the exclusive contract. Thus the appellate court found an illegal *per se* "tying" arrangement.

Recently the case of *Hyde v. Jefferson Parish Hospital District* was decided by the Supreme Court. That decision recognizes that the "tying" arrangement existed, but rejects the finding of illegality. The court held that selling medical services as a package was not a problem so long as the provider did not have enough market power in the "tying" product (hospital services) to affect competition negatively in the market for the "tied" product (anesthesia services). The crux of the matter was that the hospital controlled only 30 percent of the relevant geographic market and held no other special advantage which in conjunction with the tying arrangement threatened an unfair restraint on competition.

The result should provide solace for doctors with exclusive contracts where there are many available hospitals or service providers. However, where little competition exists, where only one hospital in an area has the necessary facilities, or where all hospitals function under exclusive contract arrangements for a particular physician service, antitrust concerns must be explored.

Conclusion

With the health care market changing more and more rapidly and further changes expected, physicians need to grasp the concepts of antitrust law so that they do not inadvertently cross the bounds of legality. The consequences of such violations or even litigation alleging violations can be disastrous in terms of legal fees, civil damages, and possibly criminal prosecution. Unfortunately antitrust law and decisions are very much geared to the particular facts of each situation. Broad generalities can be dangerous. Nonetheless physicians must be alert to the impact of antitrust law on their practice, hospital arrangements and conduct. If an antitrust problem is suspected, legal counsel clearly should be sought.

Physicians' Financial Arrangements With Hospitals

AMA CENTER FOR HEALTH POLICY RESEARCH

Over the past decade, physicians' financial arrangements with hospitals have been widely recognized as an important aspect of medical practice. Until recently, however, a lack of data has prevented a comprehensive understanding of these arrangements. In 1982, the Socioeconomic Monitoring System found that approximately one-fourth of all nonfederal patient care physicians, excluding residents had some financial arrangement with hospitals. That report also concluded that the three most common forms of compensation for those physicians with a financial arrangement were: salary, fee-for-service, and percentage of department revenue (net or gross). The purpose of this report is to provide further information on the financial arrangements between physicians and hospitals by examining the variation in these arrangements by physicians' sex, experience and income classification. The specific aspects of the physician-hospital arrangement that will be examined in this report include:

- the percentage of physicians with a hospital financial arrangement; and
- the type and frequency of these contracts.

In order to examine whether financial arrangements alter physicians' medical practice, this report concludes with a comparison of average net income, fees, and hospital utilization between physicians with and without a financial arrangement.

Physicians with Hospital Financial Arrangements

The 1984 data show very little change in the proportion of physicians with some form of financial arrangement with hospitals from the proportion reported in SMS report Volume 1, Number 2. In 1984, 24.2 percent of all nonfederal patient care physicians either received a part of their practice income by direct payment or through a lease arrangement with a hospital. In general, a larger proportion of physicians receive direct payment (19.2%) from a hospital than through a lease agreement (7.3%).

This report also examines the variation in the proportion of physicians with hospital financial arrangements by sex, experience, and net income classification. A greater proportion of female physicians (30.5%) have a direct payment contract and/or lease agreement with a hospital than male physicians (23.6%). In addition, the proportion of physicians who have some sort of financial arrangement with a hospital decreases with experience. Over 29 percent of all physicians with less than 10 years experience have a direct payment contract and/or lease agreement with a hospital, compared to only 16.2 percent of the physicians with more than 30 years experience.

Table 1
TYPE OF FINANCIAL ARRANGEMENT WITH HOSPITAL BY SEX, EXPERIENCE, AND NET INCOME[1]

	Direct Payment	*Lease*	*Lease and/or Direct Payment**
ALL PHYSICIANS	19.2%	7.3%	24.2%
Sex			
Male	18.7	7.0	23.6
Female	24.2	10.3	30.9
Experience			
0-9	22.3	10.0	29.3
10-19	19.4	6.6	23.8
20-29	18.1	5.8	22.3
30 or more	13.4	3.8	16.2
Net Income (000's of dollars)			
0-49	19.7	8.6	26.6
50-74	22.9	6.2	26.7
75-99	25.1	9.3	30.1
100-149	20.3	8.5	26.5
150-199	15.2	6.1	20.3
2OO or more	11.7	6.8	17.0

[1] Net income is defined as income after expenses but before taxes.
*The percentages reported in the first two columns do not add to the percentages reported in the third column because some physicians have both financial arrangements.

Analyzing the data by income reveals that the proportion of physicians who have a direct payment arrangement with hospitals increases for the first three income classifications and then decreases in the remaining categories. Finally, while not reported, in Table 1, our data indicates that hospital financial arrangements with physicians are most common among physicians in the Northeast.

Types of Arrangements Physicians Make with Hospitals

Table 2 analyzes only those physicians that have a direct payment arrangement with a hospital. The two most common methods through which physicians

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The AMA Center for Health Policy Research directs the socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

receive direct payments from their hospitals are salary and fee-for-service contracts. Over 60 percent of all physicians with a hospital contract have a salary arrangement, while 41.1 percent report they have a fee-for-service arrangement. Information on two alternative arrangement involving a percentage of the gross or net department billings were also collected. Table 2 shows that 7.5 percent of those physicians with hospital arrangements receive income from a percentage of net department billings while 11.8 percent received income from a percentage of gross department billings.

Those physicians most likely to have a salary contract are female physicians and physicians in the three lowest income categories. Male physicians and physicians in the three highest income classifications are the physicians most likely to have fee-for-service agreements with hospitals. In addition, physicians earning more than $150,000 are the most likely to have both a net and a gross department billings arrangement.

Practice Characteristics and Financial Arrangements

Table 3 examines income, fees, and hospital utilization for both physicians with and without a hospital financial arrangement. Overall, physicians without financial arrangements earn both a larger average net income and more income from hospital inpatient services than do physicians with financial arrangements. However, physicians charge a similar fee for a hospital visit regardless of whether they have a financial arrangement with a hospital.

An examination of the hospital utilization variables in Table 3 indicates that physicians with an arrangement spend more hours in the hospital and have more hospital rounds than physicians without financial arrangements. It appears that the largest effect of financial arrangements on hospital utilization is on the average length of stay. For patients of physicians with arrangements, the average length of stay is 15.9 days compared to only 5.7 days for patients of those physicians without arrangements. Finally, the number of patients discharged per week appears to be independent of whether a physicians has a financial arrangement.

Table 3

A COMPARISON OF PHYSICIAN INCOME, FEES, AND HOSPITAL UTILIZATION BY HOSPITAL FINANCIAL ARRANGEMENT

	Arrangement	*No Arrangement*
Income		
Average Net Income[1]	$96,400	$111,600
Net Income Derived from Hospital Inpatient Services	$51,700	$ 53,600
Fees		
Fee for Hospital Visit	$30.60	$29.40
Hospital Utilization		
Hours Work per week in a Hospital	10.6	8.0
Number of Rounds per Week	34.7	28.0
Patients Discharged Per Week	4.5	4.9

[1] Net income is defined as income after expenses but before taxes.

In conclusion, this report finds that the frequency and type of financial arrangement varies substantially by physician's sex, experience, and net income. While physicians with a hospital financial arrangement tend to utilize hospitals more and charge a high fee for hospital visits than other physicians, they also have lower average net incomes. *However, whether a physician has a financial arrangement with a hospital appears to have no significant effect on the average net income earned by a physician from hospital inpatient services.*

Information included in this report is from the annual core survey of the Socioeconomic Monitoring System. The survey consisted of interviews with 4,002 physicians from a sample representative of all non-federal patient care physicians. The survey response rate was 61.9 percent.

Table 2

TYPE OF CONTRACT FOR PHYSICIANS WITH DIRECT PAYMENT ARRANGEMENTS WITH HOSPITALS BY SEX, EXPERIENCE AND NET INCOME [1],[2]

	Salary	*Fee for Service*	*Percent of Net Dept. Billing*	*Percent of Gross Dept. Billing*	*Other*
ALL PHYSICIANS	60.4%	41.1%	7.5%	11.8%	24.2%
Sex					
Male	59.3	42.9	8.1	12.8	25.3
Female	70.3	26.7	2.7	4.1	15.1
Experience					
0-9	62.7	40.8	8.5	11.7	22.9
10-19	58.3	45.2	7.1	12.9	25.0
20-29	60.5	37.1	5.1	9.9	26.8
30 or more	56.3	39.7	9.2	13.2	24.4
Net Income (000's of dollars)					
0-49	71.8	39.3	4.8	4.8	17.9
50-74	77.7	33.6	8.1	11.8	22.2
75-99	63.7	32.1	5.9	9.7	16.9
100-149	49.6	45.6	6.7	11.0	38.2
150-199	42.0	60.8	10.0	26.0	21.6
200 or more	35.5	45.2	16.1	19.4	38.7

[1] Net income is defined as income after expenses but before taxes.

[2] The percentages reported in the table exceed 100 percent because some physicians have more than one financial arrangement.

CSMS Legislative Report

RAYMOND T. SULLIVAN, JR.

The following listing of Senate Bills and House Bills represents just a portion of the medical and health related pieces of legislation introduced in the Connecticut State General Assembly in the first seven to ten days of the 1985 session, and available to us at press time.

Members are assured that the Connecticut State Medical Society Committee on Legislation, staff and legislative lobbyists maintain close scrutiny of such bills and take appropriate and vigorous action on them. CSMS members who personally know current legislators in the Connecticut Senate and House of Representatives should notify Mr. Ray Sullivan at the CSMS office in New Haven. Such acquaintance could materially affect the outcome of the Society's legislative efforts.

SB-15 would require HMO's to provide coverage for any service which may be legally performed by any practitioner of the healing arts licensed in this state. (Introduced by Senators Gunther, Miller & Scarpetti. Insurance Committee)

SB-67 would allow an adult to execute a written declaration instructing his physician to withhold or withdraw life-sustaining procedures in the event such person should become terminally ill. (Senators Casey, Eads, McLaughlin, Miller and Representatives Carpenter, Darling & Pelto. To Judiciary Committee)

SB-104 would create a fund to help needy elderly persons pay for prescription drugs. (Senators Markham & Truglia; Human Services)

SB-120 would make otherwise skilled non-physicians eligible to be commissioner of health services in this state. (Sen. Gunther & Miller; Public Health)

SB-121 would provide for the suspension of professional licenses for convictions of fraud. (Sen. Gunther & Miller; Public Health)

SB-122 would restore certain professional licensing boards with substantive powers and duties now held by the department of human services pursuant to the "Sunset Law" of 1981. (Sen. Gunther & Miller; Public Health)

SB-128 would require the use of seat belts on school buses. (Sen. Mathews; Transp.)

SB-151 would require the commissioner of income maintenance to adopt uniform and comprehensive rate setting policies for health services provided by community health centers to medicaid patients. (Sen. Barrows: Human Services)

SB-161 would allow a retired practitioner of the healing arts to maintain a license on an inactive basis. (Sen. Gunther: Public Health)

HB-5074 would eliminate night club liquor permits. (Reps. Kezer, Polinsky, Prague: General Law)

HB-5076 would raise the drinking age to twenty-one. (Rep. Fusscas, Krawiec: General Law)

HB-5083 would raise the drinking age to twenty-one. (Reps. Migliaro, Zajac, Fusco, Antoneiit: General Law)

HB-5084 would raise the drinking age to twenty-one. (Reps. Prague, Polinsky, Anastasia, Zajac, Nystrom, Gyle, Antonetti and Sen. Gunther: General Law)

HB-5086 would prohibit "Happy Hours." (Rep. Prague, Nystrom, Kezer: General Law)

HB-5087 would regulate "Happy Hours." (Rep. Tulisano, Cappelletti, Adamo, Bowden, Nystrom, Kezer, Savage: General Law)

HB-5109 would explore the feasibility of setting up a long-term health care insurance program for residents of this state in order to provide affordable protection against catastrophic health care costs. (Rep. Cappeletti, Prague: Insurance & Real Estate)

HB-5110 would study the imposition of limits on "pain and suffering" awards and contingency fees collected by attorneys. (Rep. Chase: Insurance & Real Estate)

HB-5141 would establish a psychiatric security review board to review the treatment and progress of persons confined to a hospital for mental illness after being found not guilty of a crime by reason of insanity and

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RAYMOND T. SULLIVAN, JR., Assistant Executive Director Public Affairs and Legislation.

to make the determination as to when such persons should be conditionally released or discharged from custody. (Rep. Anderson, Nystrom, Prague, Savage, Elliott, Turek, Benson, Schoolcraft: Judiciary)

HB-5162 would create a psychiatric security review board. (Rep. Tulisano, Arthur: Judiciary)

HB-5197 would allow nurses to administer intravenous solutions in a patient's home and in nursing homes in order to fill the need to continue treatment outside the hospital due to reduced hospital stays under the prospective payment system. (Rep. Zajac: Public Health)

HB-5200 would allow physicians to use preprinted or stamped prescription forms when they wish to insure that no substitution of the drug prescribed by them will be made when the prescription is filled. (Rep. Migliaro, Fusco, Turek, Sen. Miller: Public Health)

HB-5201 would pattern the Connecticut statute on the authority of medical examiners with regard to organ transplants after the Maryland law. (Rep. Ritter: Public Health)

HB-5202 would allow a greater number of persons to qualify for the position of district director of health. (Rep. Holbrook: Public Health)

HB-5221 would require seat belts in school buses. (Rep. Chase, Adamo: Transportation)

HB-5258 would create a committee to study programs for the treatment of victims of Alzheimer's disease. (Rep. Farr: Human Services)

HB-5261 would reduce costs in the Medicaid program by (1) requiring that charges for an assistant surgeon be authorized by the primary surgeon before payment is made; (2) prohibiting weekend admissions to hospitals except emergencies; (3) limiting preoperative time in a hospital to one day; and (4) requiring preadmission lab tests. (Rep. Emmons, Turek: Human Services)

HB-5265 would encourage purchasers of medical insurance to review and scrutinize the cost of their medical treatments and to establish an 85% cap on insurable amounts for group policies. (Rep. Emmons, Turek: Insurance & Real Estate)

HB-5266 would make a person guilty of DWI when he has a blood alcohol concentration of ten-hundredths of one per cent or more of alcohol by weight. (Rep. Prague, Savage, Nystrom: Judiciary)

HB-5267 would reinstate the ad damnum clause in civil cases. (Rep. Emmons: Judiciary)

HB-5270 would impose a mandatory sentence for manslaughter with a motor vehicle while intoxicated. (Rep. Emmons, Turek: Judiciary)

HB-5277 would provide a procedure for patients to correct hospital records after they have reviewed them. (Rep. Ritter: Public Health)

HB-5278 would expand the respite care program of the department of health services. (Rep. Beckett-Rinker, Taylor: Public Health)

HB-5280 would mandate that staffing levels at state institutions for the mentally retarded be increased to the ICF-MR minimum standards. (Rep. Gionfriddo: Public Health)

HB-5281 would ensure that nursing homes have enough nurses to meet patients' needs. (Rep. Geonfriddo: Public Health)

HB-5124 would increase the penalties for minors who purchase liquor. (Rep. Cohen: Judiciary)

HB-5360 would limit the recovery for pain and suffering in medical malpractice cases. (Rep. Murdock, Fahrbach, Savage, Arthur, Baronian: Judiciary)

HB-5361 would discourage the filing of frivolous medical malpractice suits. (Rep. Murdock, Fahrbach, Savage, Arthur, Baronian: Judiciary)

HB-5362 would require that medical malpractice awards be paid on the basis of a payment schedule established by the court. (Rep. Murdock, Fahrbach, Savage, Arthur, Baronian: Judiciary)

HB-5363 would prevent exhorbitant attorneys' contingency fees in medical malpractice actions by establishing a fee schedule which would reduce the fee percentage as the award increases. (Rep. Fahrbach, Murdock, Savage, Arthur, Baronian: Judiciary)

HB-5364 would allow the admissibility of collateral source payments in medical malpractice actions. (Rep. Fahrbach, Murdock, Savage, Arthur, Baronian: Judiciary)

The President's Page

Legislation and You

The Congress on a national level and the state legislature have again begun their deliberations which will affect us all as well as our patients for years to come. It is at this time that we must all become involved directly or indirectly in this process. There are many areas in which we can become involved but two of them deserve special attention in my opinion, namely, Tort reform and altering the All Payors Legislation which is now the law of our state.

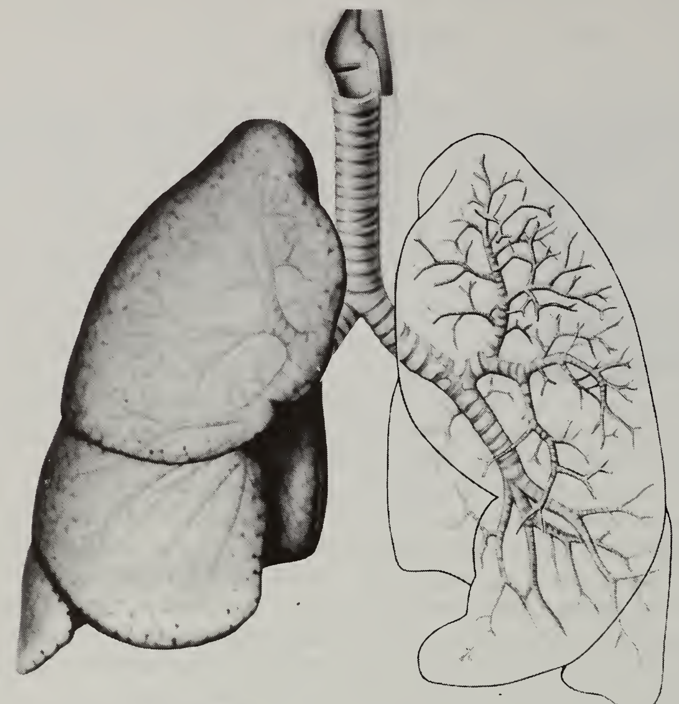
Recent rules and regulations promulgated by the Commission on Hospitals and Health Care are extremely complex as far as hospital reimbursement is concerned. A great deal of the power of the purse has been placed in the hands of the commission aided and abetted by industry and the insurance companies. I see this as a first step in an attempt to control the manner in which medicine is practiced in this state, both in the hospital as well as the office. Many physicians who have primary office practice have shown little concern for this law since it only affects hospitals. I envision a time in the not too distant future when an individual's office practice will be similarly affected. All one needs to do is look at Medicaid reimbursement policy to realize that it is not economically possible to practice high quality medicine which our patients deserve and survive, with payment policies similar to those of medicaid. As a result of this type of fiscal policy many medicaid recipients have been shunted off to clinics for care where costs are higher than if a usual and customary payment for services in a physicians office was made. We must also be diligent so that the "milk of human kindness" which has been a mainstay of patient care is not allowed to lapse and be replaced by pure monetary concerns.

Tort reform also requires our attention at this time. As physicians know and hopefully our legislators are aware, professional liability insurance premiums are a significant item in health care costs. As premiums have risen, in some cases to 10% or more of gross income, costs for care have increased as well. Unless one is independently wealthy it is almost impossible to begin a solo practice in some of the high risk specialties. The legislative committee of CSMS is making a strong effort to effect Tort reform during the current legislative session. We must convince our legislators that if current trends continue the availability and delivery of health care in Connecticut may be threatened. Several states have enacted laws concerning medical malpractice which bear study and possibly emulation. Because everyone's concerns are with cost containment for medical care, this may be an ideal time to get legislation passed in the area of Tort reform regarding medical malpractice, since this is an area of cost which needs to be controlled.

To quote Dr. Donald J. Palmisano, President of the Louisiana State Medical Society (State Health Legislation Report, Vol. 12, No. 4) "Good medical legislation does not occur by chance. It is by design." The LSMS did a number of things to implement the "design" among which included mandating that 30% of dues be dedicated to legislative activities; having full time legislative specialists on staff, and having officers of the society readily available during the legislative session for emergency decisions. To further quote Dr. Palmisano, "Like good medicine, an effective legislative approach is both an art and a science. It combines careful strategic planning and optimal tactics. Honesty and full knowledge of the proposed legislation is essential. Never fail to use the full potential of the medical auxiliary to contact legislators and physicians during legislative alerts." Should we do less in Connecticut?

Joseph S. Sadowski, M.D.
President

Consider the causative organisms...



Ceclor®
cefaclor

250-mg Pulvules® t.i.d.

offers effectiveness against the major causes of bacterial bronchitis

H. influenzae, *H. influenzae*, *S. pneumoniae*, *S. pyogenes*
(ampicillin-susceptible) (ampicillin-resistant)

Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae*, and *S pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions: *General Precautions* – If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e g , pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy – Pregnancy Category B – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly) There are, however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0 16 mcg/ml at two, three, four, and five hours respectively Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information

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Reflections on Medicine

Brain-Dusting

ROBERT U. MASSEY, M.D.

After writing this page from the dean's office for almost 12 years, and now having put decanal tasks behind me, I had trouble coming up with a new title, one that would suggest continuity with the earlier essays but would permit me some latitude in the choice of subjects. In scanning those pages, I found that most dealt either with medical education or medical history; a fair number, mostly polemical, defied easy classification, which may be a kind of judgment on their quality. For some I would feel relieved if I might apologize, but that could be seen as a kind of showy humility, unseemly in a former dean.

After almost 14 years in the dean's office I have some catching up to do. Medicine during that period of time has moved ahead incredibly fast in the development of new diagnostic and therapeutic technology. The increase in our ability to explain the way living systems work, especially in the immune system and in the nervous system, promises that the 21st century will be filled with even more surprises in science than the 20th or the 19th before it. I am told by other colleagues who have spent a decade or two in the sluggish streams of medical or academic administration that it is no good trying to catch up, that it simply cannot be done. The new biology is different and requires a whole new set of receptors in the brain. That may be, but it will be invigorating to try.

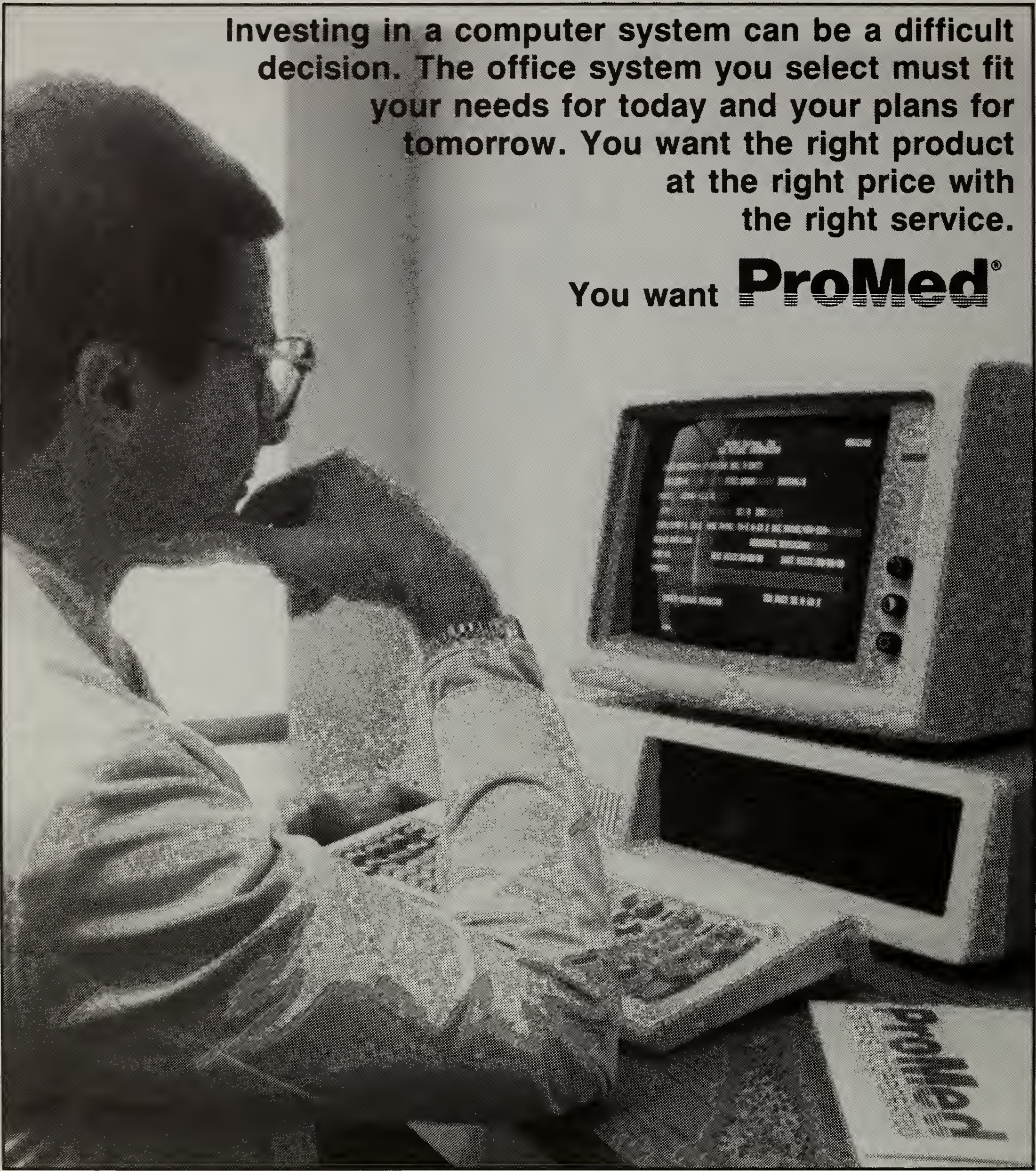
There are some other things to be accomplished and to be learned if I am to fulfill my new responsibilities as a teacher. If an aging medical academician cannot add much in the way of the new science or the new technology to his lectures and seminars, he ought at least to be able to impart some of the wisdom of experience, draw some analogies, offer a perspective or two, and quote someone from the 17th century to suggest that there are continuities against which change may be measured and judged.

That means brushing up on the humanities. Several months ago William J. Bennett, Chairman of the National Endowment for the Humanities, wrote a report on the state of the humanities in higher education, "To Reclaim a Legacy." In his opinion our colleges and universities were failing in their primary responsibility to transmit the cultural heritage of Western civilization to the generation who will be running things during the next three or four decades. The recent report of the Association of American Medical Colleges on the general education of the physician expressed similar concerns about the need "to redeem baccalaureate education from premature specialization." Medical educators have long been worried about the college preparation of students for medicine; the Bennett report makes it clear that we should have been worrying about all students and faculty members as well.

"Too many students," he wrote, "are graduating from American colleges and universities lacking even the most rudimentary knowledge about the history, literature, art, and philosophical foundations of their nation and their civilization." He listed some of the authors who "virtually define the development of the Western mind," whose works should comprise the heart of a liberal education. These writings span almost three millenia of Western history from classical antiquity to 20th century Europe and America, and of course include the Bible, "the basis for so much subsequent history, literature, and philosophy." Osler got through most of them, a half hour at a time, and spoke of the need for periodic "brain dusting."

For me there are languages to learn or relearn: Greek for one, and German, perhaps French if there is time. There is the history of science and technology, especially the history of medicine, to be studied systematically, not hit or miss the way most of us do it. There is the study of ethics and health policy, the tracing of the assumptions upon which our political masters have built the whole complex of health laws and regulations. There is no end to this, of course, but students deserve our best efforts. One of the things which medical schools always say in their mission statement is that they intend to prepare them for a lifetime of learning. Perhaps the best service we older students can render to the new is to show them how satisfying such a life can be.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.



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LAW, MEDICINE AND PUBLIC POLICY

Alcohol, Law and Public Policy: Historical Foundations

JOSEPH M. HEALEY, J.D.

Too few people in our society have been fortunate enough to escape the intrusion into their lives of the pain and suffering associated with alcoholism or caused by the use and abuse of alcohol. In our families, in our communities, we have become increasingly aware of problem drinkers and of the consequences of their problem drinking for themselves and for others. In its final report the Sixty-sixth American Assembly on Public Policy on Alcohol Problems, identified the breadth of issues involved, as well as the need for societal action:

> "Alcoholism and alcohol abuse cause American many serious problems in terms of health, safety, and the quality of life. Alcohol-related problems have their impact everywhere—homes, schools, workplaces, the military services, on highways, and even on the waters and in the air above our land. The cost is enormous, the damage widespread, the suffering severe, the magnitude growing, and the consequences incalculable.
>
> The background of relevant facts studied by the group in its deliberations included observations that alcohol-related problems (1) cost the United States more than $60 billion a year; (2) are responsible for 20 percent of the national expenditure for hospital care; (3) cause the birth of a great many disabled children every year; (4) are involved in more than a third of our suicides, half of the fatal highway accidents, a large number of rapes and sex crimes, the majority of homicides and other violent crimes, two-thirds of the deaths by drowning, 70 percent of deaths by falls, 83 percent of deaths by fire, and a majority of domestic violence episodes; (5) cause many deaths through alcoholic damage to the stomach, liver, heart, brain, and immune system; and (6) in these are various other ways kill up to 200,000 Americans a year.
>
> Meanwhile, alcoholics are still widely stigmatized, there is insufficient public awareness of the facts about alcoholism as a disease, treatment programs lack adequate funds, and research in the field does not receive appropriate support. Alcohol-related problems affect not only those who drink, but also members of their families, particularly children. Clearly, a bold new initiative is needed for the formulation of improved public policy on alcohol problems in America at all levels of government."[1]

Initiatives toward the development of such a policy are underway and there is significant interest in this area of current concern. This and the next few columns will examine some of the major legal issues involved in the development of this public policy.

One important starting point in considering these legal issues is a review of the traditional response of the anglo-american legal system to the use and abuse of alcohol. An early British statute (1606) reflects the social and cultural values which shaped the early response of our legal system:

> "AN ACT FOR REPRESSING THE ODIOUS AND LOATHSOME SIN OF DRUNKENNESS: WHEREAS, The loathsome and odious sin of drunkenness is of late grown into common use within this realm, being the root and foundation of many other enormous sins, as bloodshed, stabbing, murder, swearing, fornication, adultery, and such like, the great dishonor of God, and of our nation, the overthrow of many good arts and manual trades, the disabling of divers workmen, and the general impoverishing of many good subjects, abusively wasting the good creatures of God: II. Be it therefore enacted ... That all and every person or persons, which shall be drunk, ... shall for every such offense forfeit and lose five shillings, ... to be paid ... to the hands of the churchwardens ... (3) and if the offender or offenders be not able to pay ... shall be committed to the stocks for every offense, there to remain by the space of six hours."[2]

Alcohol abuse was treated as a sin, as a defect of the will for which the individual was to be punished. This view dominated the development of laws dealing with the conduct of intoxicated persons. Intoxication (at least voluntary intoxication) was not an acceptable legal defense to civil or criminal liability for conduct which would otherwise be the source of such liability. The law tended to be harsh, emphasizing punishment and deterrence rather than therapeutic intervention or rehabilitation. This traditional anglo-american legal response to alcoholism and alcohol abuse was challenged during the 1960's and there has emerged an alternative interpretation of alcoholism and alcohol abuse which is the cornerstone of the current efforts to establish an effective, comprehensive policy. The nature of this alternative interpretation and its implications for developing public policy will be continued in next month's column.

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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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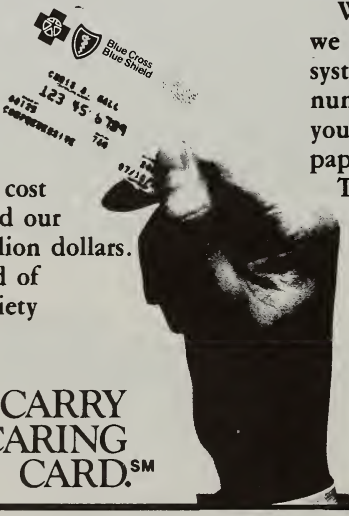

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Connecticut Medicine

The Journal of the Connecticut State Medical Society
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Editorials

The Social Kiss: A Practice Worth Discouraging?

The good ol' American "cocktail party kiss," which consisted of a greeting that involved kissing the air somewhere in the vicinity of a friend's cheek or ear, seems to have given way to a growing trend to greet even casual acquaintances with a kiss on the mouth. Sociologists could probably pinpoint an explanation for this evolving custom. My own guess is that it reflects the more open and casual sexuality of the sixties and seventies. People, particularly young people, are less inhibited about public display of affection and related emotions. The trend to kissing on the mouth as a form of greeting appears more prevalent among those in the educated and sophisticated strata of our society.

Kissing in so generous a fashion carries with it some degree of risk and has become, in fact, a public health hazard. I have seen cases of strep throats and of upper respiratory infections transmitted in this manner; and there are some more remote infection hazards, such as herpes. There is something to be said for passing up this gesture of alleged cordiality, reserving it for occasions when we mean it. First off, if done more selectively, it is bound to become more meaningful. Not that Public Health is, or should be, opposed to kissing. It becomes questionable only when the practice develops into a social ritual, one which many go along with, whether they like it or not.

If kissing among casual acquaintances is to develop into a generally accepted custom, then we would be better off using the French greeting as a role model. In France, it is customary to buss each cheek, usually the left one first. It is interesting to examine ethnic differences as they apply to such greetings. Contrasted to the two-kiss custom in France, in Belgium one kisses *three* times: left cheek, right cheek, then left again. Such local differences are remarkable. For instance, in the Loire valley of central and western France, it is customary to kiss *four* times on the cheeks: left, right, left, right.

On the continent of Europe, one shakes hands much more frequently as a form of greeting than in England. Even people who see each other daily—for example, at work—still greet each other by shaking hands each time they meet. If colleagues or friends meet frequently, the handshake takes the place of the American "Hi!" at each such meeting. This custom has not crossed the channel. There, the American way of shaking hands in a non-social environment prevails: the hand-shaking takes place only upon meeting someone for the first time, or in a new setting—not several times daily with the same individuals.

In Germany, in addition to shaking hands, one bows ever-so-slightly—not the deep bow of the Japanese. The clicking of heels is on its way out—rarely seen among the sophisticated. In Latin countries, embraces and a slight patting on the back remain the standard greeting.

Until recently, the Chinese would not even shake hands because it was considered too intimate a physical contact. Kisses as a greeting are not popular in Japan, either—not even as tokens of real affection among people who are good friends. The shaking of hands is, for the Japanese, an awkward gesture, still not well accepted except on contact with Westerners—and, even then, with some hesitancy. Instead, one delivers the traditional bow in greeting. The bowing has many subtle variations, each with an implied meaning: the deeper the bow, or the greater the number of times, the greater the respect for the individual being greeted.

The Polynesian and Eskimo custom of rubbing noses is, if anything, worse as a health hazard than is kissing on the mouth. However, rubbing noses has all but disappeared. Perhaps, before contact with the West, our common cold viruses were not around in those societies. Measles, Whooping cough and many other infections—gifts from the old world—were unknown in earlier times, but played havoc after introduction by Westerners. So, too, the common cold.

Vienna, and the territory that used to be the Austro-Hungarian Empire, still retain the old tradition of kissing a lady's hand, a practice which, in the rest of the world, lives on happily in Viennese operettas.

Hans H. Neumann, M.D.

Dr. Neumann is a Public Health physician in Connecticut.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Doctor Knows Best

This *Wall Street Journal* editorial (©1984 Dow Jones & Co., Inc.) and the following response are reprinted by permission of the authors.

You could ask the next 100 million people you meet whether giving William Schroeder an artifical heat at the Humana Heart Institute in Louisville was good or bad for the public in general and find only a single significant group of dissenters, all of whom happen to be doctors. Around the same time Mr. Schroeder was rising from his deathbed and talking about attending his son's wedding, the medical establishment was in the process of making Dr. William DeVries and Humana pariahs in the medical community.

Dr. Joseph Boyle, president of the American Medical Association, wants his membership to draw up rules to govern "the apparent commercialization of this whole process by wide-spread publicity."

Dr. David Olch of the AMA's judicial council asks, "Will the artificial heart benefit Schroeder as much as it benefits Dr. Jarvik, Humana and the surgical team?" Dr. Robert Jarvik invented the artificial heart, holds a patent on it and someday may presumably (horrible thought) profit from it. "I believe that there is a role for the federal government to play," says Dr. Olch, "perhaps the Food and Drug Administration."

Finally we have the opinion of Dr. Arnold Relman, editor of the prestigious *New England Journal of Medicine*. "It's just like a commercial organization promoting the release of a new product," said Dr. Relman, presumably communicating by telegraph from his ivory tower. "Humana has made no contributions to medical research at all. That, in my view, is not the best place to carry out this procedure."

Dr. Relman is the country's leading proponent of the idea that doctors alone should decide what's best for the public and that news of medical advances should be kept from the public until official approval is received from the informed medical community. He is currently at the center of a controversy over an unpublished article, which suggests that some early breast cancer can be treated by removing only the malignant lump rather than with a mastectomy. Dr. Relman is believed to be holding up publication of this article, whose essential findings are widely known to breast-cancer specialists. Meanwhile, many of the 115,000 women who contract breast cancer annually are left to believe their malady leaves them a single, abhorrent option. They will learn they have an alternative when Dr. Relman and his peers decide it is time to tell them.

The professional sniping now developing around the artificial-heart team reveals a similar, we-know-best mentality. It reminds us, ironically, of A.J. Cronin's young doctor in "The Citadel," challenging the medical club of another era. The irony is that Mr. Cronin was at odds with profiteering private practitioners. The wheel has turned. To solve the ever-nagging problem of securing adequate funding and freedom to work independently, Drs. DeVries and Jarvik have turned to Humana Inc. Humana is a chain of 91 hospitals that had revenues of $2 billion in 1983. Humana has said it will underwrite 100 artificial-heart implants costing up to $200,000 each. For this decision, the two doctors and their medical associates at Humana are being shunned and ridiculed by the gentlemen researchers in the "not-for-profit" community.

We surely do not gainsay the contributions made to medical science by these researchers or nonprofit institutions. But we do challenge the unseemly manner in which they are arrogating professional purity for themselves while insinuating that a Dr. DeVries in the employ of a for-profit corporation is more likely than they to make choices harmful to his patients but helpful to his wallet.

The nonprofit sector might consider addressing its own real problems rather than dreaming them up for its competitors. Dr. DeVries abandoned a state-supported institution precisely because of the excessively slow, tangled procedures the public bureaucracy wrapped him in. It's worth noting that on another part of the scientific frontier—genetic engineering—we found three federal agencies yesterday telling Rep. John Dingell they see no need for new rules to control that promising activity. Dr. Olch and his fellows in the AMA might inquire after the reasons for these bureaucrats' reluctance before pleading for yet more regulation of artificial-heart research.

The medical community's distaste for the publicity surrounding William Schroeder and the benefits that may some day accrue to Humana is not only misdirected but self-defeating. We are entering an era of discovery whose continued success will surely require the capital-building resources and ingenuity of private concerns. The continuation of this expensive process will in turn depend on the support of the public. That support will not endure if people come to believe that the medical community has decided that the accomplishments of a William DeVries are somehow improper or that fully and expeditiously disclosing news about treating breast cancer or heart disease is not in the public interest.

The following is Dr. Relman's response to the preceding editorial.

Privatizing Artificial-Heart Research

Your testy editorial of Dec. 12 ("Doctor Knows Best") confuses two subjects: the transfer of clinical trials of the artificial heart from the University of Utah to a proprietary hospital; and the value of the peer-review process by which scientific reports are scrutinized before publication in medical journals. These two subjects have little in common except your accusation that "the medical establishment" has taken the wrong stand on both, so let me briefly consider each.

You claim that Dr. William DeVries turned to a for-profit corporation for help because his efforts to pursue his work at the University of Utah were frustrated by governmental bureaucracy and lack of funds. That is a distortion of the facts, as can be easily verified by officials at the university. Over the past 15 years the University of Utah has received between $8 million and $10 million in outside support for its research on the artificial heart, mostly from the National Institutes of Health, and this support continues to finance a major research program in Salt Lake City. Furthermore, before Dr. DeVries decided to leave, the university authorities had already gathered enough funds to pay for the hospital costs of a second patient, and the local institutional review board had given its approval. It is true that this approval did not come until 15 months after the death of Barney Clark, but during seven months of that time, I am told, the board was waiting for a report from Dr. DeVries on the medical results of his first implant, and after that it was debating the difficult ethical issues raised by that case. While all this was going on, however, NIH and university officials were urging Dr. DeVries to submit an application to the NIH for support of further clinical trials. That application was never submitted, these officials told me.

The NIH has already spent about $180 million over the past 20 years on research directly or indirectly related to the artificial heart and similar cardiac assist devices. Although the rate of spending has slowed recently, NIH is still investing $13 million on this program this year. All of the basic work leading up to the development of the present model of the Jarvik heart was carried out at the University of Utah under various grants, mostly from the NIH. The university holds the patent on the drive mechanism for the heart and licensed it to Kolff Medical (now Symbion Corp.) in return for 5% equity interest in the company, 3% of all future revenues from the sale of the heart, and an agreement to support the university's research for three years. Incidentally, the implantable components of the heart itself are not patentable because the essential information about its design was published in the literature before patents were applied for.

In view of all these facts it is hard to see much justification for your view of Humana as the corporate white knight company to rescue a project that was dying for lack of support and encouragement at the University of Utah. A more accurate description, it seems to me, is that only after a massive outlay of public funds, Humana seized the opportunity afforded it when Dr. DeVries decided to leave Utah for personal reasons. In offering to pay the hospital expenses of additional clinical trials of the artificial heart, Humana was making what its own officials described as "a shrewd investment," anticipating that the long-term commercial value of the publicity would be worth many times the cost of the subsidized hospital care. So far, the investment seems to be paying off handsomely in media attention but much still depends on the ultimate outcome of the clinical trials and how the results are perceived by the media and the public.

What also remains to be seen is whether Dr. DeVries and his colleagues will be able to carry out an appropriate and detailed scientific evaluation of the artificial heart in a non-teaching, non-research hospital like Humana-Audubon. No one questions the clinical competence of the cardiac surgical team there, but much more is required than a surgical procedure and post-operative care. The artificial heart, after all, is a highly experimental device in a very early phase of its clinical development when each clinical trial must be viewed not as simply an innovative treatment but as a precious opportunity to gain new knowledge. Much scientific study will be needed to evaluate it fully, and such work is usually best carried out in hospitals that are specially equipped and staffed for clincial investigation. Will the surgical team at the Humana-Audubon be able to produce the kind of detailed in-depth studies that will substantially advance our knowledge in this field?

This brings me to the second topic of your editorial: peer review. Almost every medical investigator acknowledges the need for careful review of scientific reports before they are published, but your inflammatory statements ignore this point: You imply that the *New England Journal of Medicine* is arbitrarily delaying publication of a new report on the value of conservative surgery for breast cancer, thereby denying patients access to needed information.

There are already several published studies comparing the results of conservative surgery with traditional mastectomy, one of which appeared in the *New England Journal of Medicine* over three years ago. All doctors specializing in breast cancer are familiar with these studies and can discuss them with their patients. Physicians have also heard about the early, incomplete results of the new ongoing study mentioned in your editorial.

Before adding to the considerable literature on this highly charged and controversial subject, any responsible medical editor would want to be assured by his expert consultants that the manuscript under review significantly extended existing information and that the data had been carefully and conservatively analyzed and interpreted. Women with breast cancer, and their doctors, need reliable new information, not just any kind of information or misinformation. That is the purpose of the time-consuming peer review process—to enhance the value of the information in the medical literature, upon which we all depend.

Arnold S. Relman, M.D.
Editor, New England Journal of Medicine
Boston

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160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

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COUNCIL MEETING

Thursday, December 20, 1984
160 St. Ronan Street, New Haven, CT

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Alisberg, Beck, Bonner, Canzonetti, Dardick, Doctor, Fabro, Freedman, Friedberg, James, Kamens, McDonnell, Mendillo, Orphanos, Petrie, Ragusa, Sadowski, Scheer, Seide, Sweet, Villa, Waldron, Whalen, Jr. and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA), and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Ahamed, Ahrens, Bobruff, Czarsty, Kaess, Reyelt, Jr., Robbins, Schwartz and Sullivan, Jr.

Reports From Physicians Serving on State and Federal Agencies

Dr. Abbot reported that the Magnetic Resonance Imaging (MRI) Task Force of the Statewide Health Coordinating Council (SHCC) had been quite active and will develop a rationale and phase-in plan for the diffusion of MRI technology in Connecticut. Considerable discussion followed relating to the history of planning and implementation criteria of Computerized Tomography (CT) Scanning. It was noted that at least sixteen physicians are members of the Task Force including the co-chairman. Groups of hospitals, in the northern and southern part of the state, are forming coalitions to study the issues closely.

Dr. Whalen, President of the Connecticut Peer Review Organization (CPRO), mentioned that CPRO is located in Meriden and that as of December 15th had been involved with Pre-Admission and Pre-Procedure Review. He welcomed members to visit CPRO at anytime. Drs. Canzonetti and Mendillo cited the effectiveness of the Pre-Admission Certification Programs at New Britain Hospital and the HMO Health Care in New Haven.

Dr. Van Syckle commented on two items of interest from HSA V in Waterbury; Dr. Eslami's CT Certificate-Of-Need application for private office utilization in competition with two other applications, and the shortage of nursing home beds in the Fairfield-Danbury areas. He noted that a report from the Commission on Hospitals and Health Care (CHHC), was forthcoming in late January on the subject.

Report of the President

a) *CMIC*

Joseph S. Sadowski, M.D., apprised the Council of the hiring by the Connecticut Medical Insurance Company of Brown Brothers Harriman & Co. as investment counselor. There had been twelve firms considered for the responsibility which had been pared down to four before Brown Brothers Harrison & Co. was selected.

Jerome K. Freedman, President of CMMI, mentioned that the umbrella policy binders had not been issued yet by CMIC but that all physicians who had signed up for such coverage were protected.

b) *Prospective Payment Regulations*

Dr. Sadowski reported on a hearing before the State Commission on Hospitals and Health Care on December 14 in which complicated regulations were presented. The regulations use algebraic formulas to determine how each hospital in the state would be paid, based on the diagnosis of the patient. President Sadowski testified on behalf of CSMS against the regulations and was joined in his opposition by the Connecticut Hospital Association and the AFL-CIO.

Roger S. Beck, M.D., introduced a motion which has been approved by the Hartford County Medical Association pertaining to the regulations. It was VOTED to approve the following motion: "That the CSMS go on record to support CHA's efforts to clarify, as well as to simplify the proposed regulations for P.L. 84-315." It was also VOTED to authorize the President and Staff to submit testimony by December 28 opposing the establishment of a statewide central registry for physicians' codes.

c) *Pre-Admission Certification*

Finally, Dr. Sadowski detailed a two hour meeting held 12/20/84 with Peter Gillies, Insurance Commissioner, State of Connecticut, to hear and comment on CIGNA's attempt to institute a Pre-Admission Certification and Continued Stay Review Program in its group insurance contracts.

Report of the Executive Director

Tim Norbeck reported on the AMA Convention with specific reference to the action taken urging a ban on boxing, and distributed articles relating to the boxing ban, rationing of medical care and the AARP confrontation with medicine.

AMA Convention Report

A brief summary of actions taken at the AMA Convention was distributed to the Council and members of the delegation commented on the various issues which included discussions on HMOs, hospital and medical staff relations, AARP, PROs, unified membership, chelation therapy, medical education and public relations.

1) *Unified Membership*

After a discussion of unified membership (membership in county, state and AMA), the following actions were taken:

a) VOTED that the Council recommend to the CSMS House of Delegates that unified membership be invoked in Connecticut.

b) VOTED to recommend to each county medical association that it initiate actions to work towards the goal of unified membership in Connecticut.

c) VOTED to request the CSMS staff to secure informational materials from the AMA helpful to the counties in promoting unified membership.

Legislation

Jerome Bobruff, M.D., Chairman of the CSMS Committee on Legislation, was unable to attend the Council meeting. In his place, Isadore H. Friedberg, M.D., reported on a meeting held on December 18 by the Committee on Legislation as follows:

1) The committee intends to go forward with an aggressive program in the tort reform field and will introduce bills primarily concerning collateral source and periodic payments. Other goals are caps on nonmonetary damages and contingency fees. It was VOTED to support the action of the Legislative Committee in this regard.

2) The Council took the following action on other legislative bills:

VOTED that CSMS become a member of the Coalition on Seat Belts.

VOTED to endorse a ban on Happy Hours, Uniform Closing Hours and Drinking Age of 21.

VOTED to support the Wearing of Helmets by motorcycle riders.

VOTED not to introduce any legislation banning boxing and to offer the Society's services to the Boxing Commission.

3) Kenneth Dardick, M.D., thanked the Council for the contribution of $200.00 to the Seat Belt Coalition and mentioned that its office would open in the near future.

Progress Report on Podiatry Issue

CSMS Staff members reported on a hearing held by the Podiatry Board on November 7, 1984 regarding expansion of the scope of podiatric practice. CSMS attorneys and members attended the hearing and testified. Following is an excerpt from the report of CSMS Legal Counsel: "Testimony presented at the hearing established that the foot and ankle are anatomically separate and that the ankle cannot be considered treatment of 'foot ailments.' Treatment of the ankle is therefore beyond the statutory scope of practice of podiatry in Connecticut as established by section 20-50."

It was VOTED to receive the report as information and with commendation.

Discussion of the Ongoing Relationship Between Connecticut General and the Physicians of Connecticut

A recommendation was received from the CSMS Committee on Third Party Payments that a Liaison Committee be re-established between CSMS and Connecticut General for the purpose of improving communications between Connecticut General and the practicing physicians concerning the Medicare operation.

Dr. Charles Polivy, medical consultant to Connecticut General, and Barbara Wimbish, manager of Beneficiary Services to Connecticut General made brief presentations regarding Medicare's reimbursement policies and protocols established by the Health Care Financing Administration (HCFA) and the problems encountered by both Connecticut General and physicians with the transition from the RVS system to the CPT-4 reimbursement methodology. The Connecticut General representatives recommended that a Liaison Committee be established to attempt to alleviate some of these situations.

It was VOTED to form an Ad Hoc Committee to function as a liaison group with Connecticut General on matters relating to the Medicare Program. It was suggested that some members of the committee on Third Party Payments, be on the committee and that location and specialty be a consideration.

It was VOTED further to empower the Chairman of the Council at his discretion to appoint members of the Liaison Ad Hoc Committee.

Proposed Meeting with State of Connecticut Workers' Compensation Commission

Marvin S. Arons, M.D., recommended to the Council that CSMS hold a meeting with the nine commissioners of the Workers' Compensation Commission of Connecticut in order to discuss issues of mutual concern regarding the Workers' Compensation Program.

It was VOTED to form an Ad Hoc Committee of seven physicians to meet with the commissioners of the

Workers' Compensation Commission with the intention of developing an ongoing relationship between the two bodies. It was agreed that the committee should reflect geographical and specialty consideration.

Dr. Van Syckle, Chairman of the Council, appointed the following Ad Hoc Committee: Drs. Marvin S. Arons, Chairman, New Haven, Andrew J. Canzonetti, New Britain, Patrick J. Carolan, Bridgeport, Richard T. Sweet, Middletown, Joseph S. Sadowski, Hartford and Charles P. Marshall, Stamford.

Public Affairs Program (Referred by House of Delegates 11/15/84)

William A. Whalen, M.D., discussed a public affairs program for Connecticut and mentioned the AMA program which had been debated at the AMA House of Delegates.

After discussion, it was VOTED to refer the recommendation of the CSMS Committee on Public Affairs for a $30,000.00 public information media program back to the Committee on Public Affairs for more specific information and details. It was agreed that CSMS staff would secure whatever help is available from the AMA staff.

Report on Meeting of the Council of New England State Medical Societies

It was VOTED to receive for information the reports of Drs. Jerome K. Freedman and W. Raymond James. It was VOTED also to endorse Melvyn Gelch, M.D., (Rhode Island) as a recipient of the Benjamin Rush Award and to support the candidacy of John Ayres, M.D., (Massachusetts) for the AMA Council on Long Range Planning and Development.

Date of 1985 Semi-Annual Meeting

It was VOTED to hold the 1985 CSMS Semi-Annual Meeting at the Ramada Inn in North Haven on November 20, 1985.

Date of Next Meeting

The Council will meet on March 21, 1985.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on December 20, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

LIFE MEMBERS

Effective Date: January 1, 1985

It was VOTED to receive for information the following list of Life Members.

Name	**Town**
Richard S. Bagnall	Bloomfield
Arnold H. Becker	Bristol
John D. Bolton	Greenwich
Russell S. Bower	New Britain
Carl Butenas	Meriden
Robert K. Butterfield	Bolton
Benjamin Cohen	West Hartford
Edward J. Conway	Hartford
Mark Conway	West Hartford
Ronald W. Cooke	Hartford
Albert H. Dolinsky	New Haven
George Dorfman	New Britain
Michael Dzubaty	West Haven
James R. Fitzgerald	West Hartford
Charles T. Flynn, Jr.	Meriden
Edward J. Flynn	Norwalk
Frederick J. Flynn, Jr.	Glastonbury
William L. Gates	Wallingford
David D. Giardina	Westport
Archie J. Golden	Wethersfield
John H. Houck	Hartford
Harry A. Inder	Bridgeport
Michael Jacuch	Hartford
Henry M. Kaplan	New Britain
Harold J. Lehmus	Manchester
Clarence J. Lipkoff	Milford
William H. Lohman	Glastonbury
Frank Lovallo	Sharon
Einar A. Lundberg	Fairfield
Irwin T. Mancall	Hartford
Saul B. Meltzer	Bridgeport
John J. Mendillo	Branford
Anthony J. Parisi	New Haven
Orlando Pelliccia	New Haven
Paul S. Pizzo	Hartford
Ludwig J. Pyrtek	Hartford
G. Lucille Rucker	Storrs
Robert D. Russo, Sr.	Bridgeport
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The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

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FAMILY PRACTICE

July '85. Licensed in Connecticut. Age 35. Nat'l bds. AB cert. MD, Albert Einstein College of Medicine, New York, NY; Int. and Res., University of California, San Francisco, CA. Prefers group or HMO, Community Health Center. Write, John V. Quarrier, M.D., 62 Dalerose Court, Daly City, CA 94014.

Immediately available. Presently in practice. Age 39. MD, Bangalore Medical College, India; Int., Victoria Hospital, Bangalori; Res., Herts & Essex General Hospital, Bishop's Stortford, U.K. Prefers group or associate type practice in a small-sized community. Write, MSU/FP, c/o CSMS.

Aug. '85. Age 27. Nat'l bds. MD, St. Louis School of Medicine, Saint Louis, MO; Int. and Res., Saint Mary's Hospital, Milwaukee, WI. Prefers group or associate type of practice in a small to medium-sized community. Write, Thomas J. Federico, M.D., 1570 N. Prospect Ave., #108, Milwaukee, WI 53202.

Aug. '85. Age 29. Nat'l bds. AB elig. MD, University of Washington, Seattle, WA. Int. and Res., Thomas Jefferson University Hospital. Prefers group type practice in a medium-sized community. Write, John K. Porter, M.D., 33 Lafayette Ave., Haddonfield, NJ 08033.

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July '85. Age. 31. AB elig. MD, Universidad Autonoma de Guadalajara, Mexico; Int., Overlook Hospital, Summit, NJ; Res., Highland Hospital, Rochester, NY (IM); St. Joseph's Hospital, Syracuse, NY (FP). Seeking full-time Emergency Medicine. Less than 20,000 visits/year, in a medium-sized community. Write, Daniel Yacono, M.D., P.O. Box 6821, Syracuse, NY 13217.

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July '85. Age 27. Nat'l bds. AB elig. MD, Medical College of Virginia, Richmond, VA; Int. and Res., Medical University of South Carolina, Charleston, SC. Prefers group or associate type practice in a medium to larged-sized community. Write, Bruce A. Silverman, M.D., 3 Sawgrass Rd., Apt. F-1, Charleston, SC 29412.

Jan. '85. Age 29. AB elig. MD, Universidad del Caribe, Cayey, Puerto Rico; Int. and Res., St. Vincent's Medical Center. Prefers group or associate type practice. Write, Dominic F. Mazzocchi, M.D., 1231 East 89th St., Brooklyn, NY 11236.

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HEMATOLOGY/ONCOLOGY. July '85. Age 37. Nat'l bds. AB cert. MD, Kyung Hee University, Korea; Int. and Res., St. Luke's Hospital, Bethlehem, PA; Fellowship, University of Illinois Hospital, Chicago, IL. Prefers solo, group, associate or institutional type practice in a medium to large-sized community. Write, Hoon Park, M.D., 112 W. 65th St., Westmont, IL 60559.

July '85. Age 44. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, University of Missouri; Int., Kings County Hospital, Brooklyn, NY; Res., Kings County Hospital and University of Minnesota Hospitals; Fellowship, Hartford Hospital (Yale affiliate GI). Wishes to join a group of internists or purchase a practice in the greater New Haven area. Write, Michael A. Rosenthal, M.D., 4808 Longridge Ave., Apt. 112, Sherman Oaks, CA 91423.

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July '85. Age 31. FLEX. AB elig. MD, Autonoma de Guadalajara University, Mexico; Int. and Res., Upstate Medical Center, Syracuse, NY. Special laser and colposcopy trained. Prefers group or associate type practice in a small to large-sized community. Write, Nesim Contente, M.D., 7300 Cedar Post Rd., Apt. 10E, Liverpool, NY 13088.

Immediately available. Presently in practice. Licensed in Connecticut. Age 48. FLEX. AB cert. MD, San Marcos University, Lima, Peru; Int., The Hospital of St. Raphael, New Haven, CT; Res., St. Elizabeths Hospital, Brighton, MA. Experienced in infertility microsurgery. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Augusto E. Midolo, M.D., 265 Riverside Dr., Binghamton, NY 13905.

July '85. Age. 26. Nat'l bds. AB cert. MD, Hahnemann University, Philadelphia, PA; Int., St. Raphael's Hospital, New Haven, CT; Res., Danbury Hospital, Danbury, CT. Seeking to join a group or associate type practice. Write, Les A. Burns, M.D., 6 Essex Court, Brookfield, CT 06804.

PATHOLOGY

Immediately available. Licensed in Connecticut. Age 37. Nat'l bds. AB cert. MD, New York Medical College; Int., Yale-New Haven Hospital; Res., University of California, Sacramento, CA. Prefers group, associate or institutional type practice in a large-sized community. Write, Leslie Dowd, M.D., 36E Grove St., Manchester, CT 06040.

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Dec. '84. Age 31. Nat'l bds. AB elig. MD, NY Medical College, Valhalla, NY; Int., Res. and Fellowship, St. Vincent's Hospital and Medical Center of New York, NY, NY. Prefers group or associate type practice. Write, Nicholas G. Bonvicino, M.D., 130 West 12th St., Apt. 5-J, New York, NY 10011.

July '85. Age 33. Presently in practice. FLEX. MD, University of The West Indies, University Hospital of The West Indies; Int., Res. and Fellowship, Harlem Hospital Center (affiliated with Physician & Surgeons, Columbia). Prefers group, solo, or associate type practice in that order. Write, Derrick J. Martin, M.D., 13-2 Granada Crescent, White Plains, NY 10603.

July '85. Age 29. Nat'l bds. AB elig. MD, Trinity College, Dublin, Ireland; Int., Sir Patrick Duns Hospital, Ireland; Res., Washington Hospital Center, Washington, DC. Will consider any type practice. Write, Karl W. Sorenson, M.D., 6724 Conway Ave., Takoma Park, MD 20912.

July '85. Age 28. Nat'l bds. AB elig. MD, Int. and Res., Albany Medical College, Albany, NY; Prefers group or associate type practice in a medium-sized community. Write, Francis Siracusa, M.D., 229 Morris St., Apt 6A, Albany, NY 12208.

Sept. '85. Age 30. Nat'l bds. MD, Int. and Res., University of Massachusetts Medical School, Worcester, MA. Fellowship, The Willima Harvey Hospital, England. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Richard D. Zlotnik, M.D., 21 Heywood St., Worcester, MA 01604.

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July '85. Age 34. Nat'l bds. AB elig. MD, Cornell University Medical College, New York, NY; Int. and Res., Medical College of Virginia Hospitals. Prefers solo, group or associate type practice in a medium-sized community. Write, Richard Tushman, M.D., 519 Vantage Place, Richmond, VA 23236.

July '85. Age 32. MD, Hospital of India; Res., Brookdale Hospital, NY; Res., University of Minnesota. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Binod Sinha, M.D., 3425 Golf View Dr., Eagan, MN 55123.

Gestational Trophoblastic Neoplasia in Southern Connecticut: The Experience of the Yale Trophoblastic Center, 1971-1983

ERNEST I. KOHORN, M.D., TRUDY KEATING, R.N., MARTHA BLOOD, R.N.,
JOSEPH T. CHAMBERS, M.D., PH.D., AND PETER E. SCHWARTZ

ABSTRACT—During the period 1971 to 1983, 212 patients with gestational trophoblastic disease were seen at the Yale Center for trophoblastic disease. Fifty one patients developed nonmetastatic gestational neoplasia and all these were cured. Seven patients presented with metastatic disease, five to the lung and two with widespread metastasis. Six of these seven patients were cured and the one who died did not receive primary therapy at a Trophoblastic Disease Center. The changing criteria of diagnosis and management of trophoblastic disease are discussed.

Ten years ago we reported in this Journal our initial experience of the management of hydatidiform mole and trophoblastic neoplasia.[1] We have continued to be a resource for consultation and referral in Southern Connecticut and have based our practice on the philosophy that the qualified gynecologists in consultation with a Trophoblastic Disease Center is fully capable of treating uncomplicated hydatidiform mole but that neoplasia is preferably treated at the Trophoblastic Disease Center, whose staff is conversant with the idiosyncratic problems that may arise in this unique disease.[2] During the past 13 years we have seen or consulted on 212 patients with gestational trophoblastic disease.[3] We here describe the advances and changes that have occurred with gestational trophoblastic disease in the past decade and report the 61 patients with trophoblastic neoplasia treated at the Yale Trophoblastic Center. The criteria which led to the diagnosis and the management of these patients are presented.

Definitions

Gestational trophoblastic disease designates a group of patients with hydatidiform mole and gestational trophoblastic neoplasia. It has now been demonstrated that hydatidiform mole may be complete or partial.[4] Complete hydatidiform mole has an androgenic basis for its chromosomal constituents in so far as all chromosomal material from the ovum is extruded and is replaced by the genetic material of the sperm chromosome. Most complete hydatidiform moles are therefore XX, some are X-Y but cell having Y-Y chromosomes may not survive. A complete hydatidiform mole has avascular villi and no associated fetus. There is associated trophoblastic hyperplasia and a 15-20% incidence of neoplasia. With partial hydatidiform mole the villi may have vessels and there is frequently a malformed fetus usually with a triploid or trisomic chromosome pattern or sometimes a mosaic chromosomal pattern. There is little trophoblastic hyperplasia and the incidence of subsequent neoplasia is 2-4%.

Diagnosis and Management of Hydatidiform Mole and Associated Complications

When we reported the management of hydatidiform mole in southern Connecticut for the period of 1972-1979,[3] the diagnosis was made by ultrasound in only 57% of 127 moles. It is remarkable that in the last five years, 90% of moles have been diagnosed by ultrasound. A few early moles are still diagnosed when the products of conception are examined histologically, particularly following termination of pregnancy. A combination of the techniques of ultrasound scanning, for the detection of the presence of the fetal heart, together with human chorionic gonadotropin (hCG) evaluation in early abnormal pregnancy associated with threatened miscarriage, is providing a higher accuracy in the diagnosis of molar pregnancy.

ERNEST I. KOHORN, M.D., Professor, Gynecology & Obstetrics; Director, Yale Center for Trophoblastic Disease. TRUDY KEATING, R.N., Nurse Practitioner, Gynecologic Oncology, Yale-New Haven Hospital. MARTHA BLOOD, R.N., Gynecologic Oncology Nurse, Yale-New Haven Hospital. JOSEPH T. CHAMBERS, M.D., PH.D., Assistant Professor, Gynecology & Obstetrics. PETER E. SCHWARTZ, M.D., Associate Professor, Gynecology & Obstetrics; all from the Yale Center for Trophoblastic Disease, Department of Obstetrics and Gynecology, Yale University School of Medicine, New Haven, CT.

Supported by the Baumer Fund of Yale University.

Reprint requests to: Department of OB/GYN, Yale University School of Medicine, 333 Cedar St., New Haven, CT 06510 (Dr. Kohorn).

Romero, et al.[5] have demonstrated that the fetal heart becomes detectable by ultrasound when the hCG level reaches 70,000 milli iu per ml. Molar vesicles are frequently not resolved by ultrasound prior to the 8th week of pregnancy.[6] If the fetal heart is not detectable and there is a significantly elevated hCG above 70,000 at about 8 weeks of gestation, it is likely that a hydatidiform mole is present. If by ultrasound there is no fetal sac or no fetus in successive examinations, the pregnancy will require evacuation in any case. The diagnosis of partial hydatidiform mole has been more difficult to establish until late in the first trimester but it is being aided by the technique of combining sonar and hCG evaluation.

Hydatidiform mole may now be divided into high and low risk categories for malignant sequelae.[7,8] Patients who have a uterus large for dates by more than 4 weeks gestational age, who have a significantly high hCG titer at the time of mole evacuation and those who have theca-lutein ovarian cysts, have a 50% chance of developing trophoblastic neoplasia requiring chemotherapy. The other high risk factor for neoplasia in molar disease is previous pulmonary embolization; the risk appears to be 90% or greater.

Hydatidiform mole is a condition that resolves spontaneously following molar evacuation in 80-90% of patients. Gestational trophoblastic neoplasia is preceded by hydatidiform mole in some 50% of cases, but 40% follow abortion and 10% follow previous apparently normal pregnancy. Gestational trophoblastic neoplasia is diagnosed on the basis of persistently elevated hCG values after hydatidiform mole or apparent miscarriage or following the investigation of uterine bleeding or of metastases in a woman during reproductive life. Gestational trophoblastic neoplasia (GTN) is nonmetastatic when clinical examination and simple investigation, such as radiology, CT scan or isotope scan fails to show metastases. This classification supercedes the previous classification of choriocarcinoma, chorioadenoma destruens and metastasizing mole. Metastatic neoplasia is classified as high risk or low risk.[9] Low risk GTN is associated with an hCG titer of less than 50,000 milli iu per ml, less than 4 months from the termination of the last known pregnancy or is diagnosed if the metastases are confined to the lung. The criteria of high risk metastatic disease are listed in Table 1. Low risk metastatic disease may be treated with single agent chemotherapy; high risk metastatic neoplasia requires triple therapy.

Table 1

CRITERIA FOR HIGH RISK GESTATIONAL TROPHOBLASTIC NEOPLASIA

1. Beta hCG greater than 50,000 milli iu per ml more than 4 months, from termination of the hydatidiform mole or the last known pregnancy.
2. Brain Metastases
3. Liver Metastases
4. Metastases after previous full term pregnancy
5. Previous inadequate treatment.

Methods

Following mole evacuation patients were followed by serial weekly hCG beta subunit estimations using a sensitive radioimmunoassay. The assay used was a 3 day radioimmunoassay accurate to 2 milli iu per ml. In order to obtain occasional more speedy information we have used an 8 hour radioimmunoassay, in use in our department for diagnosis of pregnancy and monitoring ectopic gestations. While the values of hCG by these 2 assays usually shows fairly close agreement between 1,000 and 70,000 milli iu per ml there is divergence above and below these values. A speedy assay is usually not accurate at levels below 20 milli iu per ml. Particular difficulty may arise with referred patients who have a persistantly elevated titers or persistant symptoms after hydatidiform mole as there may be substantial variation in values of hCG among different laboratories. It is essential that physicians who follow patients with hydatidiform mole use a sensitive hCG radioimmunoassay.

The values of hCG are plotted on 5 log graph paper as demonstrated in Figure 1. Plotting such a graph is mandatory in following patients with trophoblastic disease as only sequential falls are associated with significant resolution of the mole or of neoplasia. The usual definition of trophoblastic neoplasia throughout the United States is an elevation of hCG of 3 plateau values over 2 weeks following mole evacuation. While accepting this for hCG values above 10,000 milli iu per ml, it has been our practice with values below 10,000 milli iu per ml to make a diagnosis of neoplasia only if the plateau persists for 4 values over 3 weeks before commencing chemotherapy.[10]

A confidence curve of sequential fall of hCG has been constructed (Figure 2) and values of an individual patient are plotted against this confidence curve so that an early divergency of the fall of hCG may be recognized. It is usually clear by 4 or 5 weeks following mole evacuation, whether or not a patient is likely to require chemotherapy.

Results

Table 2 shows a summary of all diagnoses of the patients seen from 1971 to 1983. One hundred and eighty nine patients had hydatidiform mole and 121 of these resolved satisfactorily as assessed by clinical examination and serial hCG estimations.

In this group of patients with hydatidiform mole only 10% of patients required blood transfusion. Seven patients developed endometritis which was satisfactorily controlled by antibiotics. Five patients had mild preeclampsia and one patient had significant postpartum preeclampsia.

Five patients with mole (2.6%) developed pulmonary embolization of molar tissue.[11] All patients who developed pulmonary embolization of trophoblastic tissue had a uterus greatly enlarged for gestational age and had a high hCG. With this significant complication of mole there can be gross deterioration of pulmonary function in a previously healthy young woman, either before or immediately after mole evacuation. In one patient the diagnosis was not recognized for several days and she was treated with a diagnosis of pneumonia until it was realized that a hydatidiform mole was present. Management in all patients involved evacuation of the uterus, monitoring of cardiac output by use of a Swan-Ganz catheter and measurement of pulmonary ventilation parameters. Each patient responded to therapy with oxygen, morphine sedation and steroids. Positive pressure ventilation in an intensive care unit was necessary in 3 of the 5 patients. None of the patients who had pulmonary embolization of molar tissue developed pulmonary metastases, although all developed persistantly elevated hCG titers leading to a diagnosis of nonmetastatic gestational trophoblastic neoplasia requiring chemotherapy.

Prophylactic chemotherapy was used in 11 of the patients in the initial phase of the study. This practice was abandoned as patients could be followed carefully by hCG titers and would be treated only when indicated thus avoiding unnecessary administration of chemotherapy to 8 out of 10 patients.

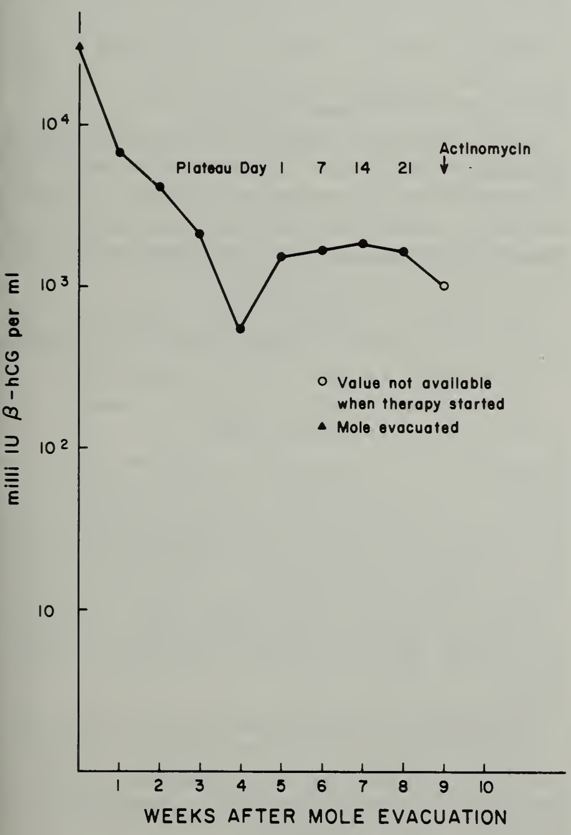

Figure 1
Patient followed by serial weekly hCG values following mole evacuation. Plateau of hCG with some rise at 5, 6, 7, 8 and 9 weeks. Chemotherapy then commenced with resolution following 2 courses of actinomycin-D. This patient was followed longer than usual and she would usually have been treated after 3 weeks of plateau at values of hCG between 10^3 and 10^4.

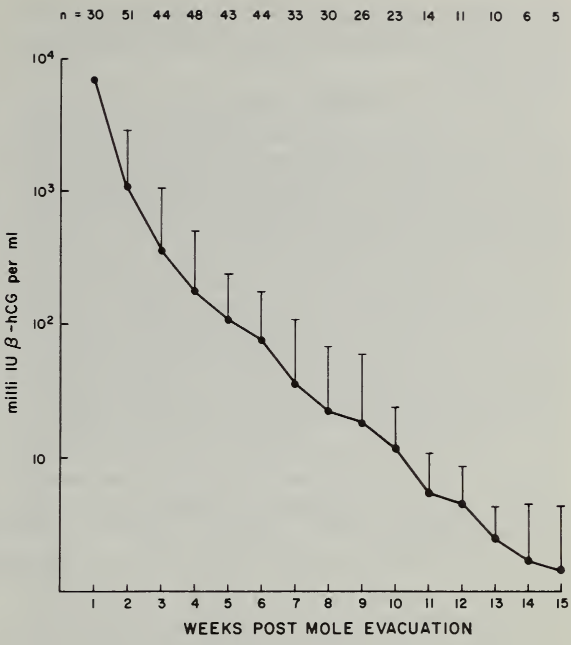

Figure 2
The Confidence curve of β-hCG used to follow patients after mole evacuation.

Table 2
CLINICAL DIAGNOSIS OF PATIENTS SEEN AT
YALE CENTER FOR GESTATIONAL TROPHOBLASTIC DISEASE 1971-1983

Diagnosis		*Number*
Hydatidiform mole		189
Moles, no sequelae	121	
Moles, prophylactic chemotherapy	11	
Moles, with nonmetastatic trophoblastic neoplasia	50	
Moles, with metastatic trophoblastic neoplasia	7	
Choriocarcinoma uterus		5
Partial Mole		16
Focus Abnormal Trophoblast in Placenta		1
Ovarian Hydatidiform mole		1
Total		212

Nonmetastatic Gestational Trophoblastic Neoplasia

Fifty patients developed nonmetastatic gestational neoplasia following hydatidiform mole and 7 patients developed metastases, only 2 of which were extra pulmonary. There were 16 partial moles. Three patients presented with primary choriocarcinoma of the uterus. One of these followed a termination of pregnancy, one appeared to be primary and one followed a full term pregnancy. Two patients developed trophoblastic neoplasia after full term pregnancy and both these showed pulmonary metastases.

One patient presented with a hydatidiform mole in the ovary. Following oophorectomy the hCG spontaneously reached undetectable levels. [12] A further patient had a histologic focus of abnormal trophoblast in the placenta following a fetal demise at 26 weeks with an associated hCG of 8 million milli iu per ml. She was treated by hysterectomy and the hCG reached nondetectable levels uneventfully.

All patients with nonmetastatic gestational neoplasia achieved remission without major difficulty. The primary drug used was actinomycin-D, 12 μgm/kg and all but 4 patients were primarily treated with this medication. The mean number of courses required was 3. The occasional patient with a low initial hCG plateau required only 1 course of treatment while several patients required 4 or 5 courses of treatment. If the value of hCG was above 50,000 milli iu per ml a further course of treatment was given as soon as the patient's condition and her white cell count and platelets allowed, usually 2-3 weeks. If the hCG value at the beginning of treatment was below 10,000 milli iu per ml and the hCG was falling satisfactorily between therapies, the interval between courses was extended to 4 weeks. In this way, a more acceptable and lower toxicity was achieved. Seven patients were treated by sequential methotrexate-actinomycin D, by one of the investigators, as initially advocated by Julian Smith.[13] There appeared to be no difference in the speed of remission in these patients and the toxicity was slightly higher. Five patients were treated with primary methotrexate and 2 patients with methotrexate with leucovorin rescue.[14] The latter regimen requires 8 days of therapy instead of the 5 days with the actinomycin-D. Logistically, we have found little advantage and not much more toxicity by using actinomycin-D, rather than methotrexate.

Metastatic Gestational Neoplasia

During the 13 years of this study, there were 7 patients who had metastatic gestational trophoblastic neoplasia. Five patients had lung metastases only and their disease readily responded to single agent chemotherapy except for one patient, where the lung metastases developed during therapy for apparent previous non-metastatic disease, treated by single agent chemotherapy. This lady responded to two courses of triple chemotherapy. Two patients had widespread metastases at initial presentation. One patient, presented following a pneumonectomy and also had brain, liver and tongue metastases. She required 5 courses of combination chemotherapy with methotrexate, actinomycin D and cyclophosphamide. She was in hospital for 6 months. She is now well with a longer than 5 year follow-up. The other patient was initially treated for pulmonary metastases using a relatively low course of chemotherapy at another hospital. She was then lost to follow-up and a year later was referred to the Trophoblastic Disease Center with widespread metastases. After numerous courses of several chemotherapy regimens, she finally succumbed to her disease, inspite of the fact that she had a relatively low level of hCG.

Five patients developed primary choriocarcinoma of the uterus. Three of these followed an apparent full term pregnancy and it is interesting that all three patients presented with persistant postpartum bleeding and had a fetus that was anemic. This danger signal for the presence of choriocarcinoma needs to be recognized by obstetricians. One patient developed choriocarcinoma following termination of pregnancy at 8 weeks gestation. She was treated by primary hysterectomy with "actinomycin-D cover." One patient, presenting as a missed abortion, had a "primary choriocarcinoma" in the uterus. This patient was resistant to treatment with methotrexate, then actinomycin-D and failed to obtain remission following hysterectomy. She was finally treated with triple therapy with good results.

Thus, of the 55 patients with nonmetastatic disease and the 7 patients with metastatic disease, there has been one death associated with persistent metastatic trophoblastic neoplasia.

Discussion

This experience with trophoblastic disease appears remarkable for the fact that diagnosis of hydatidiform mole in southern Connecticut is now being made early in the disease and that both ultrasound and hCG evaluation are being used by obstetricians and gynecologists, such that one rarely sees a patient with an advanced hydatidiform mole with its associated complication of hemorrhage, infection or pre-eclamptic toxemia. The technique of combined ultrasound, fetal heart monitoring and hCG evaluation in the first trimester will further aid in such early diagnosis of mole.

Patients who have an enlarged uterus in association with hydatidiform mole, have usually been referred to the Trophoblast Center for evacuation of the mole and careful monitoring of their cardio-pulmonary status, so that the major complications associated with pulmonary embolization were only severe in one case.

Following the evacuation of a hydatidiform mole, gynecologists in southern Connecticut have been fastidious in following their patients with hCG estimations and have usually consulted with the Trophoblastic Disease Center if there has been any problem. In this way, a plateau or an elevation of hCG has been recognized early and, following referral, treatment has been initiated promptly. It is remarkable that in this group of 189 patients with hydatidiform mole, only 7 developed metastases and that only 2 of these were widespread. Thus, only 2 of these 7 cases had high risk metastatic gestational trophoblastic neoplasia. It is noteworthy that the one patient who died was initially not treated at the Trophoblastic Disease Center.

Trophoblastic neoplasia remains the one human cancer curable by chemotherapy when recognized and treated expeditiously. Clinical alertness, ultrasound and hCG estimation and prompt expeditious chemotherapy are necessary to effect such cures.

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Carcinoma of Unknown Primary: A 20 Year Retrospective Analysis

MARC S. ERNSTOFF, M.D. AND ROSE J. PAPAC, M.D.

Abstract—Twenty-eight patients with histologically documented carcinoma of unknown primary site were evaluated retrospectively to assess clinical and laboratory observations that were of predictive value in survival outcome. Primary site of origin was diagnosed in 14 of 28 patients, antemortem (21%) and 8 additional patients at postmortem. The most common primary site was lung, followed by gastrointestinal tract. Good prognostic factors include performance status ≤ 2 (ECOG scale, $p = 0.016$) and peripheral WBC ≤ 9000/cu mm ($p = 0.039$). Median survival was five months with a range from eight days to ten years.

These observations suggest that the initial assessment of patients presenting with malignant disease of obscure origin should be directed toward commonly occurring tumors, depending upon the clinical status of the patient.

Introduction

Metastatic carcinoma presenting as an unknown primary tumor constitutes from 0.5% to 7% of patients with neoplastic disease.[1] The prevailing view of such cases is that median survival varies from six weeks to six months; that there is a low rate of detection of the primary site antemortem and a thorough search for a primary may be unwarranted.[2,3] While the general opinion suggests the outcome for patients with an unknown primary tumor is bleak, we have occasionally observed instances of long survival in such cases. We have reviewed the experience in this hospital over the past two decades to assess clinical and laboratory observations that had an impact on survival, the frequency of antemortem detection of the primary site, and which combination of findings may warrant investigation for a primary source.

Materials and Methods

From 1962 until 1982 there were 46 out of 6,000 cancer patients at the West Haven Veterans Hospital who were classified as carcinoma of unknown primary site, although only 29 cases proved to actually be such on review. This represents 0.48% of our cancer population. These were patients who were admitted with the clinical evidence of metastatic neoplasm, and whose physical examination and history, as well as admission laboratory studies including CBC, urinalysis, SMA-20 and chest roentgenograms failed to disclose a primary site. Of the 29 patients, histologic confirmation of malignancy was obtained in all but one, who was excluded from analysis. In this instance, presumptive

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MARC S. ERNSTOFF, M.D., Assistant Professor of Medicine, Section of Medical Oncology, Department of Internal Medicine, Yale University School of Medicine. ROSE J. PAPAC, M.D., Associate Professor of Medicine, Department of Internal Medicine, Yale University School of Medicine; Chief of Hematology and Oncology, West Haven Veterans Administration Hospital, West Haven, CT.

Reprint requests to: Section of Medical Oncology, Yale University School of Medicine, 333 Cedar Street, New Haven, CT 06510 (Dr. Ernstoff).

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diagnosis was based upon overwhelming radiologic evidence of multiple large nodular lesions on a chest film.

The survival outcome was assessed with respect to age, race, performance status, histology, number of organs involved at diagnosis, impact of specific organ involvement (namely bone marrow, liver or brain), time interval to diagnosis and therapy. These factors were evaluated using multiple factor regression analysis, the Cox method.[4,5] Symptoms, because of subjectivity, were excluded from analysis. Additionally, we reviewed the utility of diagnostic methods and determined the number of cases in which the diagnosis was obtained either ante or post mortem.

For patients who presented with adenocarcinoma, unknown primary site, special stains for mucin and PAS were carried out. All mucin positive cases had a gastrointestinal evaluation including stool guaiac, and upper and lower GI series. Three out of five cases had either sigmoidoscopy or colonoscopy performed. Full lung tomograms were performed in five patients. For mucin negative cases intravenous pyelogram (IVP) was done in ten patients. Two patients underwent blind prostatic biopsies. Patients with adenocarcinomas with positive PAS stain had IVP evaluation. Epidermoid tumors presenting as unknown primary had careful examination of the head and neck region.

Results

Reflecting the population of this institution all but one patient was male. The age, sex, and racial characteristics are shown in Table 1. The mean age at diagnosis was 59 ± 8.5 years. The median survival was five months with a range from eight days to ten years. There are four patients alive at 12, 19, 24 and 45 months. The survival curve (Figure 1) shows a rapid decline to the median, but beyond one year survival shows a gradual decline with 25% alive at 18 months and three of 28 (10%) at five years.

Table 1
PATIENT STATISTICS

	Total	Survival ≤ 6 Months	Survival > 6 Months
# of patients	28	16	12
Age	59	62 ± 8.3	56 ± 7.8
Sex M/F	27/1	15/1	12/0
Race			
B	7	4	3
W	21	12	9
PS	1.8	2.6 ± .96	.92 ± 1.16

The most frequent tissue diagnosis was adenocarcinoma in 18 of 28 cases (64%) (Table 2). Undifferentiated carcinoma was the next most frequent (five patients) followed by squamous cell carcinoma (three patients), fibrous histocytoma (one patient) and salivary gland tumor (one patient). The patient with salivary gland tumor was initially diagnosed as an undifferentiated carcinoma; subsequent review of the slides led to the accurate diagnosis.

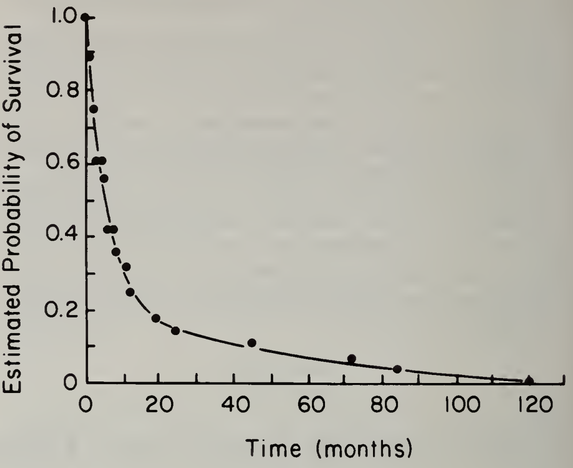

Figure 1
Overall survival curve (n = 28).

Table 2
TUMOR HISTOLOGY

	Total	(%)	Survival ≤ 6 Months	Survival > 6 Months
Adenocarcinoma	18	(64)	11	7
Undifferentiated Carcinoma	5	(18)	3	2
Squamous Carcinoma	3	(11)	2	1
Fibrous Histiocytoma	1	(3.5)	0	1
Salivary Gland Cancer	1	(3.5)	0	1

The histologic pattern of the tumor did not appear to be a significant determinant of survival. The longest survivor was a patient with a tumor originally classified as "undifferentiated" but on review at our institution proved to be adenocarcinoma. The primary site was salivary gland, confirmed by examination of tissue removed from the submaxillary gland, presumed to be benign five years before presentation with metastases to lung and bones. Making the premortem diagnosis in six patients did not appear to influence survival. On the other hand, survival correlated with the primary site found (Table 4), but not with therapy.

Table 4
SURVIVAL OF PATIENTS WITH PREMORTEM DIAGNOSIS OF PRIMARY SITE

Site	Histology	Survival from 1st Diagnosis of Cancer
Salivary gland	Adenocarcinoma	10 years
Epiglotic fold	Squamous	6 years
Prostate	Adenocarcinoma	1 year +
Lung	Adenocarcinoma	8 months
Pancreas	Adenocarcinoma	2.5 months
Lung	Adenocarcinoma	2 months

The impact of various parameters on survival is shown in Table 3. Neither the number of organs clinically involved nor specific sites (bone marrow, liver or brain) had an impact on survival, although actual number of cases is small.

Table 3
SITES OF DISEASE

	Total	*(%)*	*Survival* ≤ 6 Months		*Survival* > 6 Months	
Number of Organs Involved	2.7		2.0 ± 1.9		2.9 ± 2.2	
BM/Liver/Brain Involved	17	(61)	8	(50)	9	(75)
Total Diagnosed	13	(46)	2	(12.5)	5	(42)
1 ° Diagnosed Antemortem	7	(28)	8/11	(73)	4/5	(80)
Diagnosis at Postmortem (Diagnosis/Post's Performed)	12/16	(75)				
Primary Sites						
Lung	6		5		1	
Colorectal	2		1		1	
Pancreas	2		1		1	
Gastric	1		1		1	
Epiglottic Fold	1				1	
Salivary Gland	1				1	
Prostate	1		1			

The most significant factor affecting survival outcome was the performance status at the time of diagnosis. Patients whose performance status was two or less (ECOG scale) as shown in Figure 2, had superior long term survival. The median survival of patients with good performance status is about twice as long as those with poor initial performance status ($p = 0.016$). At five years, 3/17 patients with good performance were alive, while by two and a half years all patients with performance status greater than two had died.

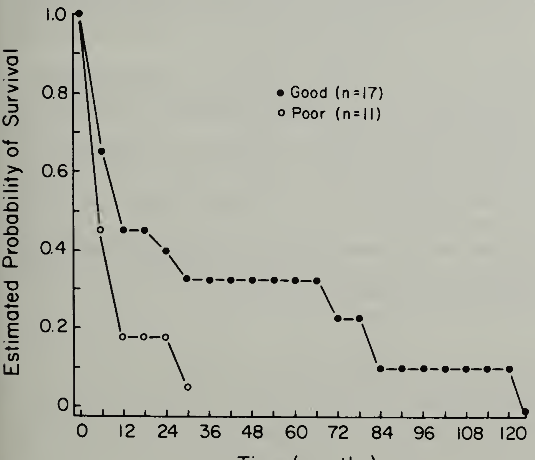

Figure 2
Survival based on performance status (PS).
Good PS ≤ 2 (•, n = 17), poor PS (0, n = 11).

The laboratory parameters which were examined included peripheral blood count values and blood chemistries. The blood chemistries were highly variable and no significant trend could be defined though elevations of LDH portended a poor prognosis generally. The peripheral white blood cell (WBC) count value was found to be a prognostic variable of significance. Patients with leukocytosis of greater than 9000/cu mm had a median survival of five months, while those with normal or decreased WBC count values had a median survival of 12 months ($p = 0.039$) (Figure 3). Leukocytosis and poor performance status were independent prognostic indicators.

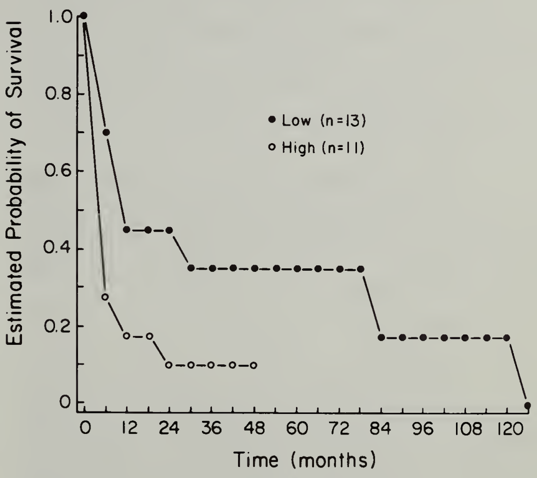

Figure 3
Survival base on peripheral WBC.
WBC ≤ 9,000 cells/cu mm (•, n = 13).
WBC > 9,000 cells/cu mm (0, n = 11).

The median time from presentation to diagnosis was 14 days (range 0 to 365) and had no correlation with prognosis. Diagnosis of the primary site was established in 14 of 28 patients with diagnosis in six (21%) patients antemortem confirmed in two at postmortem and additional eight patients diagnosed at postmortem evaluation.

Discussion

In this retrospective analysis of carcinomas of unknown primary origin, our findings indicate the median survival is brief (five months). The determination of primary site was achieved antemortem in 21% and postmortem in an additional 42%. The commonest primary site was lung and it is noteworthy that there were no cases of melanoma, undifferentiated lymphoma nor testicular malignancy.

Factors which did not influence survival included specific metastatic site, age, interval from diagnosis of malignancy, and histologic tumor type. The two patients with brain metastasis lived for 10 and 19 months—both significantly longer than the median. Tumor invasion of the bone marrow or liver similarly did not influence survival; one patient with involvement of both sites from pancreatic carcinoma survived 18 months. In fact, of 16 patients with involvement of either bone marrow or liver, eight survived beyond the median. The factors which did influence outcome were performance status and level of peripheral white count. Leukocytosis was usually associated with infection (6/10) which was considered the cause of death in nine patients.

The clinical evaluation of patients with carcinoma of unknown primary tumors is a controversial topic.[6-19] The recommendation, based upon a low yield of detection and short survival, in one study[3] is not to pursue an intensive search for a primary site. On the other hand, it is suggested by Moertel that a judicious assessment of these cases is warranted.[20, 21]

Based upon our observations indiscriminate screening with tests directed toward detection of rarely occurring tumors is not appropriate. The rationale for investigation of patients with good prognostic indices in the hope of detecting tumors likely to benefit from antineoplastic therapy as illustrated by a gentleman with metastatic prostate who responded symptomatically to hormone manipulation. As therapy changes and improves the possibility exists for improving both quality and length of life in these patients.

Newer scanning techniques with the use of conjugated monoclonal antibodies, or NMR may offer greater accuracy in localizing sites of tumor, as well as indicating the primary tumor site more frequently. Additionally, therapeutic advances may contribute to successful management of such cases. Our findings suggest that at the present time, a defined cohort of patients with carcinomas of unknown primary site at initial presentation, merit investigation as well as supportive and palliative management.

Acknowledgements

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Intracranial Extramedullary Hematopoiesis in Polycythemia Vera

GEORGE A. ROBITAILLE, M.D., MARC EISENBERG, M.D.
AND ROBERT LEHMAN, M.D.

Abstract—Extramedullary hematopoiesis is a well recognized complication of chronic myeloproliferative diseases. Intracranial involvement with this lesion is rare but radiosensitive and treatable. A patient with polycythemia vera developed neurologic symptoms that were initially thought to represent transient ischemic attacks exacerbated by thrombocytosis. Computerized tomographic scanning followed by 99mTc sulfur colloid brain scanning led to an autopsy confirmed diagnosis of intracranial extramedullary hematopoiesis.

Intracranial extramedullary hematopoiesis has been reported on rare occasions in patients with chronic myeloproliferative diseases.[1,2] Both intrathoracic and intracranial extramedullary hematopoiesis has been identified with 99mTc sulfur colloid scanning.[3,4] However, we were unable to find reports of autopsy confirmed cases of intracranial extramedullary hematopoiesis having been detected with sulfur colloid scanning. The following case of polycythemia vera presented this finding and emphasizes the need for considering this diagnosis in all patients with myeloproliferative diseases.

Case Report

A 68 year old right handed white man was admitted to the hospital one hour after experiencing a grand mal seizure at home.

Five years prior to admission he was diagnosed as having polycythemia vera. At that time his hematocrit was 63% and hemoglobin was 21.5 grams %, with a white cell count of 12,300 and platelet count of 392,500. His uric acid was 9.3 mg. % and the spleen was enlarged. His leukocyte alkaline phosphatase score was increased to 290. A bone marrow examination revealed marked erythroid hyperplasia and overall hypercellularity. He was repeatedly phlebotomized during the following months and years in order to keep his hematocrit below 50%. Except for one episode of gastrointestinal bleeding from a duodenal ulcer, his clinical course was unremarkable.

One year prior to admission the patient underwent neurologic evaluation for repeated episodes of lightheadedness and vertigo. A computerized axial tomographic (C.T.) scan revealed some ventricular dilatation but was otherwise normal. Because of his thrombocytosis of 753,000 he was suspected of having repeated "small strokes" and he was placed on aspirin 648 mg. twice a day and chlorambucil 4 mg. daily.

Two months prior to admission he complained of difficulty using his right hand along with repeated episodes of expressive aphasia. His platelet count remained increased at 709,000. The aspirin was discontinued and warfarin was added to his regimen at this point with apparently good control of his prothrombin times. His symptoms seemed to improve slightly. Six weeks prior to admission he experienced the sudden and complete loss of function of the right arm and to a lesser extent his right leg. Again these symptoms spontaneously remitted until the time of the present admission.

Physical examination on this admission found him to be oriented but with slurred speech and minimal aphasia. He had moderate weakness in the right arm but normal strength in both legs. He had some increase in tone of the right upper extremity. Sensory examination was normal. Reflexes were normal except for a probable Babinski on the right side. Cerebellar examination was poorly tested but appeared to be within normal limits. The remainder of his physical examination revealed moderate splenomegaly and was otherwise negative. Laboratory studies revealed a prothrombin time of 24.2 seconds with a control of 12 seconds. The white blood cell count was 15,800, hemoglobin 14.1 grams %, hematocrit 43.8 and platelet count 754,000. Serum electrolytes, blood urea nitrogen, amylase, lipase, creatinine, liver function tests, calcium, phosphorus and urinalysis were all within normal limits. Electrocardiogram and chest x-ray were normal. An electroencephalogram revealed a slight excess dysrhythmic left temporal theta activity. He was given phentyoin and the warfarin was reinstituted after discharge from the hospital. A computerized axial tomographic (C.T.) scan was subsequently obtained as an out-patient and this revealed multiple lesions with a pattern suggesting metastatic tumor. The most prominent lesion was in the high left anteroparietal region (Figure 1 left). There were similar lesions in the lower left parieto-occipital region as well.

Two weeks later he was readmitted to the hospital with the sudden onset of right hemiparesis and aphasia. His prothrombin time was 70 seconds which was immediately corrected to 18 seconds with the administration of vitamin K dependent factor concentrate. A repeat C.T. scan revealed evidence of an intracranial hemorrhage in addition to the previously described lesions on the C.T. scan ten days earlier. Following the intravenous injection of 15 mc of 99mTc sulfur colloid, gamma imaging of the head was obtained (Figure 2). It demonstrated extension

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GEORGE A. ROBITAILLE, M.D., Assistant Clinical Professor of Medicine, Yale University School of Medicine; Associate Chief of Medicine, St. Mary's Hospital, Waterbury, CT. MARC EISENBERG, M.D., Assistant Clinical Professor of Laboratory Medicine, Yale University School of Medicine; Attending Pathologist, St. Mary's Hospital. ROBERT LEHMAN, M.D., Attending Radiologist, St. Mary's Hospital.

of bone marrow activity into the facial bones and multiple focal areas of increased activity which appeared to be intracranial and to correlate with the lesions seen on the earlier C.T. scan. His level of consciousness rapidly deteriorated and he expired on the third hospital day.

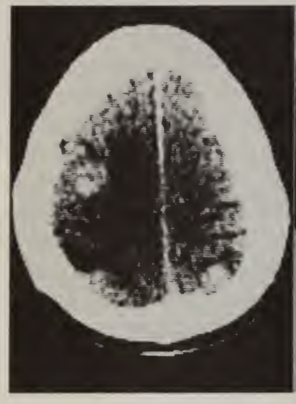
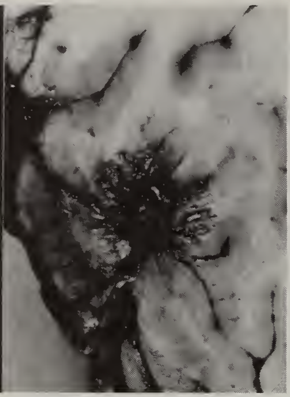

Figure 1 (left)
Computerized tomographic head scan with multiple tumor nodules seen bilaterally in cortical and sub-cortical regions. Principle lesion is in left antero-parietal region.

Figure 1 (right)
Gross section through left cerebral cortex. This is thought to be the same large lesion that is seen in fibure 1 (left) and is indicated by the marker in figure 2 A and D.

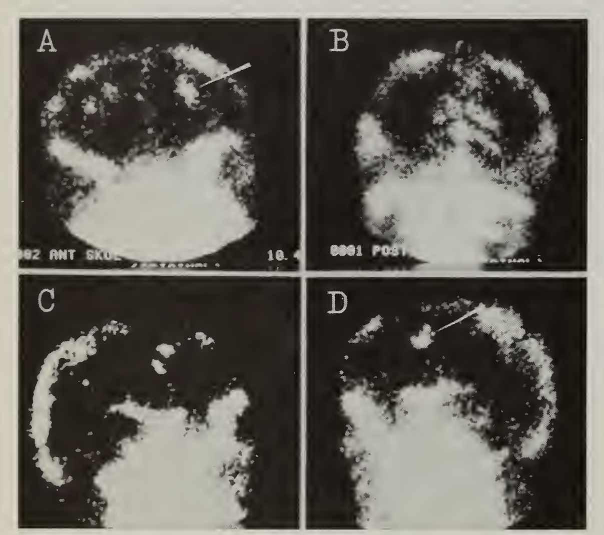

Figure 2
99mTc sulfur colloid brain scan. Multiple lesions are noted and marker points to lesion that is illustrated in Figure 1, left and right. (A) anterior view (B) posterior view (C) right lateral view (D) left lateral view.

Post mortem examination was limited to the head. A large blood clot was present on the left occipital lobe. The dura over the left post-erior aspect of the brain, in the vicinity of the cerebellum, revealed an ill-defined soft mass measuring 1.0 cm. Touch imprints of the cut surface revealed megakaryocytes, immature granulocytes and nucleated red cells. Hematoxylin and eosin stained sections revealed proliferative fibroblastic cells and megakaryocytes. After fixation, serial coronal sections revealed a massive intracerebral hemorrhage within the left cerebral hemisphere. The cerebral cortex contained multiple focal lesions involving the graymatter and extending into the whitematter. (Figure 1 right). These were bilateral and ranged in size from 0.5 to 1.0 cm. The lesions had a tan or yellow granular surface. Some had a stellate appearance with a depressed central area. Sections of these focal cortical lesions reveals the same findings as noted above. The brain tissue surrounding these lesions showed some gliosis and hemosiderin laden macrophagias.

Comments

Central nervous system involvement with extramedullary hematopoiesis is usually extradural and paraspinal.[5,6] On rare occasions it has been reported within the cranial dura mater, including the choroid plexus.[1,2] The histology of these lesions include all the components usually seen in myeloid metaplasia sites. Megakaryocytes, erythroid and myeloid precursors, fibrosis and sclerosis are the rule.[7] In our case, Wright Giemsa stained imprints of the dural lesions revealed megakaryocytes, immature granulocytic cells and nucleated red cells. Hematoxylin and resin stained sections of these lesions as well as the focal cortical lesions revealed fibroblastic proliferation mixed with megakaryocytes. These findings were very similar to those often seen in the bone marrow of patients with various myeloproliferative diseases.

Theories explaining the origin of extramedullary hematopoiesis are as varied as the basic diseases in which it is found. These include activation of embryonic rests, direct extension from existing bone marrow and embolization from distant marrow sites. Recent experimental data suggests that the latter mechanism may be operative in patients with polycythemia vera.[9]

The cellular composition of these lesions is important in considering the various isotope techniques that are used to identify bone marrow or extramedullary sites of hematopoiesis. In normal man, the ratio of phagocytic to erythropoietic cells is relatively constant, but variation in this ratio occurs in a variety of pathologic states.[8] Although erythroid elements were present in our case, the primary cellular component was reticuloendothelial. These elements are easily detected by isotope labeling utilizing 99mTc sulfur colloid which is readily available in most nuclear medicine departments. The erythropoietic elements can be labeled with radioiron which is the most specific isotope used. Fe 59, which is readily available, has very high energy and as a result requires massive collimators. This makes it a poor imaging agent. Fe 52 is far superior as an imaging agent but is cyclotron produced and not readily available in most hospitals. It is also expensive, short lived and requires a positron camera for optimal imaging. We therefore recommend CT scanning followed by sulfur colloid isotope scanning when considering this diagnosis.

Extramedullary hematopoiesis occurs in many patients with chronic myeloproliferative diseases at some time during the course of their illnesses.[7,10] Since local extramedullary hematopoietic tumor masses are often reduced or eliminated with radiation therapy, it is essential that the clinician remain alert to this possibility when treating patients with these diseases.

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A New Sample Collecting and Testing System for the Detection of Occult Blood in Feces

STEPHEN C. WARDLAW, M.D., ROBERT A. LEVINE, M.D., HOWARD M. SPIRO, M.D.

AND CYNTHIA JOHNSON, R.N., B.S.

ABSTRACT—Hemawipe* is a new system for the detection of fecal occult blood that allows direct anal stool sampling and incorporates a means of semi-quantitatively metering stool onto guaiac impregnated test paper. The direct sampling method was developed to increase the likelihood of a patient completing the test, and the metering system was designed to facilitate reading the test results. In a comparison study with 75 volunteer subjects, Hemawipe showed a greater ability to detect simulated upper gastro-intestinal bleeding than did Hemoccult II.** In a second study group of 54 subjects with hemorrhoidal disease, Hemawipe's direct anal stool sampling method did not produce false positive results. Both study groups voiced an 9:1 preference for the Hemawipe system over Hemoccult II, a preference which could result in greater compliance and therefore earlier detection of potentially curable lesions.

Introduction

The utility of examining the feces for the presence of occult blood has been well-documented,[1] but the utility is blunted by a relatively low compliance rate among asymptomatic persons in returning stool samples. A recent study in an asymptomatic population reported a return rate of between 8.6% and 28.7%, depending upon different motivations within the study group.[2] Although such low compliance may be due to a fear of finding that a disease is present, we suspect that many of the non-returns are due to patients' reluctance to handle feces. Another manifestation of poor compliance is the tendency of some patients to use samples from one stool to fill all of the test cards. This defeats the purpose of multiple sampling, which is to obtain samples from successive bowel movements.[3] Similarly, we have found that a number of fecal occult blood tests ordered on hospitalized patients are not performed, no doubt in part due to the adversion of both patient and staff to handling fecal material.

An additional problem with guaiac slide methods comes from variations in the amount of feces placed onto the collection device; this contributes to the considerable observer variability in interpreting test results,[4] particularly when the stools are dark.

STEPHEN C. WARDLAW, M.D., Clinical Professor, Department of Laboratory Medicine, Yale University School of Medicine. ROBERT A. LEVINE, M.D., Associate Clinical Professor, Department of Laboratory Medicine, Yale University School of Medicine. HOWARD M. SPIRO, M.D., Professor, Department of Medicine, Section of Gastroenterology, Yale University School of Medicine. CYNTHIA JOHNSON, R.N., B.S., Head Nurse, Coronary Rehabilitation, Yale New Haven Hospital, New Haven, CT.

Professors Wardlaw, Levine and Spiro, inventors and developers of Hemawipe, have a commercial interest in the product.

Reprint requests to: 960 Main St., Branford, CT 06405 (Dr. Levine).

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*Hemawipe is a registered trademark of Med Tech Products, Inc., Miami, FL 33014

**Hemoccult II is a registered trademark of SmithKline Diagnostics, Inc., Sunnyvale, CA 94086

Transportation and handling of the currently used slide tests also creates difficulties. It is illegal to mail test cards containing feces,[5] and sanitary hazards have been created when this has been done despite the postal regulations.[6] Because of this, the samples must be brought back by the patient to the office or laboratory for testing; this additional inconvenience to the patient no doubt further decreases the rate of returns.

This paper describes a new method of stool sample collecting and testing which improves the esthetic and sanitary considerations of stool collection and sample disposal. Along with the increased ease of reading the test results, these improvements should benefit both compliance and disease detection.

Description of the Device

The design goals of the Hemawipe system are to: (1) allow the patient to collect the sample in a non-offensive manner, (2) produce uniform samples in a pattern which allow the results to be easily read, (3) provide a means of ensuring a sanitary seal so that the samples could be legally mailed and safely handled and tested, and, (4) provide a means for sanitary disposal after testing is completed.

Figure 1a shows the Hemawipe prior to use. It consists of a pliable, waterproof backing to which is attached a piece of guaiac-impregnated paper. On the collection side of the Hemawipe, over the area of the guaiac paper, the thin, tissue-like covering is perforated with 38 holes, 2mm in diameter. After defecating, the patient wipes the anus with this collection surface, smearing the stool residue through the perforations and onto the guaiac paper. The tissue cover is then peeled off by the patient (Figure 1b), leaving the metered stool sample as a pattern of dots. This gives a relatively constant sample/guaiac ratio as well as creating a distinctive pattern which is easily read. The tissue layer is made from soluble paper which is safely flushable. When the tissue is removed, an adhesive backing surrounding the guaiac paper is exposed so that the device may be folded to create a sealed pouch (Figure 1c). The tissue removal also uncovers a small area of heme control material and brings it into apposition with the guaiac paper. When the device is completely sealed in this manner, it can be safely and legally mailed.

When the sealed device is received, a resealable window on the reverse is opened, and the developing reagent (hydrogen peroxide in ethanolic solution) is added to the guaiac paper over the collection area. If the sample is positive, the hemoglobin and resultant blue color migrate away from the stool dot(s), forming blue streaks or halos. This gives a distinctive "starburst" effect (Figure 2) to a positive sample. After the result is read, a drop of developer may be added to the control area to ensure that the paper and developer are functional. When the readings are finished, the window may be resealed for sanitary disposal of the device.

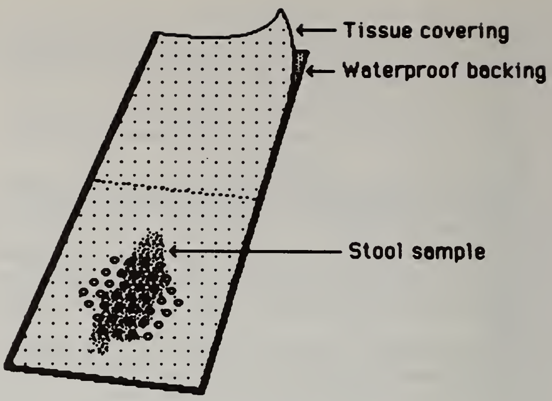

Figure 1a
Hemawipe with stool smeared on collection area.

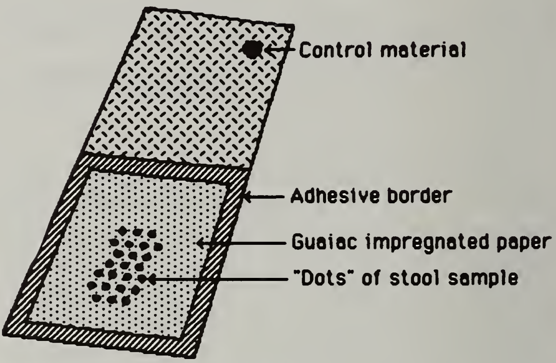

Figure 1b
Appearance after removal of tissue layer, showing "dots" of stool screened onto guaiac paper.

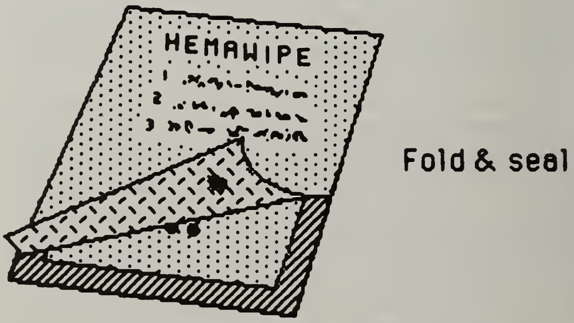

Figure 1c
Folding forms a sanitary seal and brings the control material into contact with the guaiac paper.

Hemawipe was compared to the widely used Hemoccult II (Smith Kline Diagnostics, Inc.) in two specific areas. First, *in-vitro* and *in-vivo* studies were designed to determine if the dispersed stool pattern in Hemawipe caused a decrease in sensitivity and second, the results of stool sampling in patients with verified hemorrhoids were examined to detect any tendency of anal stool sampling to initiate hemorrhoidal bleeding. In addition, a questionnaire was distributed to all subjects, asking them to state their preference for either the direct stool collection (in a plastic cup), the Hemoccult II, or the Hemawipe.

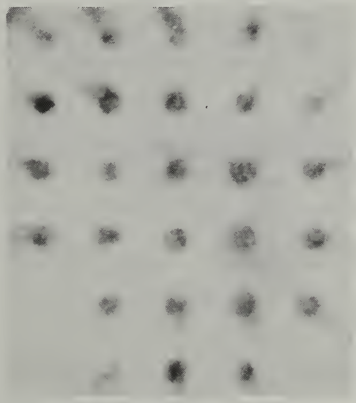

Figure 2

A typical 2+ reaction showing the hemoglobin migrating away from the stool "dots."

Materials and Methods

Eighty normal volunteer subjects, drawn largely from the professional medical community, submitted solid stool samples, and a completed Hemawipe and Hemoccult II (Lot #1128) from the same bowel movement. The solid samples were tested on filter paper by a stabilized guaiac-oxidizer liquid reagent (SRG) with the same *in-vitro* sensitivity as that of the Hemawipe. This was done to determine if observed differences between the Hemawipe and Hemoccult II were due to the method of collection or to chemical sensitivity. No specific dietary regimen was requested except the standard recommendation to avoid raw vegetables and rare meat. Of this group, 5 were initially positive and were not included in subsequent testing (Table 1). The test group of 75 subjects was 41% male and ranged in age from 19 to 62 years.

Table 1

RESULTS OF PRE-STUDY SCREENING

	HEMOCCULT II	*HEMAWIPE*	*SRG***
NEGATIVE	78	75	75
TRACE	0	2*	3*
1+ or Greater	2†	3†‡	2†

† 2 cases—Menstrual bleeding
* 2 cases—Presumed dietary causes
‡ 1 case—Bleeding hemorrhoids
**Stabilized guaiac reagent used for chemical sensitivity comparison.

Table 2

GRADING OF GUAIAC COLOR REACTION

Grading	*Description of Reaction*
Neg.	No color at any time, up to one minute.
Trace	Any color, no matter how evanescent or faint, appearing at any time.
1+	A faint but clearly discernible color, appearing after about 30 seconds.
2+	Clearly noticable color appearing within 30 seconds and darkening to strongly visible by one minute.
3+	Strong color developing within 15 seconds.
4+	Strong color developing immediately.

The subjects were given 30 ml of freshly drawn autologous whole blood mixed in 250 ml of tomato juice. Stool samples were collected for the next four consecutive bowel movements, and the time of each collection was recorded. To minimize the effect of reader variation, all testing was performed by one person. Although it is not recommended by the manufacturer, we elected to describe the results in a semiquantitative manner; the grading system we used is shown in Table 2. The Hemoccult II reaction monitors and the Hemawipe control were developed immediately following each test.

In the second phase of the study, we selected 54 additional subjects who had physical evidence of hemorrhoids but no reported intercurrent gastrointestinal disease. These subjects collected samples from a single bowel movement in the same manner as the first group. This group was 24% male and ranged in age from 22 to 71 years.

The sensitivities of the methods were also compared *in vitro*. To determine the effect of the stool matrix on the ability of the methods to detect fresh hemoglobin, a set of samples was created by mixing hemoglobin into solid stool. These samples were smeared on the test cards and developed after a one hour delay. This testing procedure was repeated using stool emulsions, which were prepared by mixing the solid samples with an equal weight of normal saline.

Results

Table 1 shows the results of stool testing before the blood ingestion. Of the 80 subjects, 75 had negative stools by all methods, two were positive by two methods due to menstrual bleeding, one was positive by all methods because of actively bleeding hemorrhoids, and two were positive by two methods, presumably for dietary reasons, as subsequent samples were negative.

Table 3

REACTIVITY OF STOOLS AFTER INGESTION OF BLOOD

	POSITIVE STOOLS Trace to 4+			
Bowel Movement # (after ingestion of blood)	1	2	3	4
Number of Specimens	73	74	72	73
	Number (and percent) of Positive Stools			
Hemoccult II	9 (12.3)	24 (32.4)	15 (20.8)	13 (17.8)
Hemawipe	31 (42.5)	58 (78.4)	48 (66.7)	34 (46.6)
SRG	31 (42.5)	51 (68.9)	50 (69.4)	38 (52.1)
	POSITIVE STOOLS 1+ to 4+			
Hemoccult II	6 (8.2)	9 (12.2)	9 (12.5)	6 (8.2)
Hemawipe	26 (35.6)	49 (66.2)	38 (52.8)	23 (31.5)
SRG	22 (30.1)	45 (60.8)	42 (58.3)	25 (34.2)

Table 3 shows the reactivity of the stools after ingestion of blood. Although the timing is different for each subject, the results show the expected rise and fall of positive reactivity. The overall detection rates are shown in Table 4 and Figure 3 as a function of cumulative positive results following each bowel movement. Table 5 and Figure 4 show the cumulative results as a function of the time after ingestion that a positive stool was passed.

Table 4

CUMULATIVE POSITIVE RESULTS VS STOOL NUMBER

Stool #	*1*	*2*	*3*	*4*
	Cumulative number (and percent) of positive conversions			
Hemoccult II	6	13	19	21
(%)	(8.1)	(17.6)	(25.7)	(28.4)
Hemawipe	27	56	60	63
(%)	(36.5)	(75.7)	(81.0)	(85.1)
SRG	23	53	63	64
(%)	(31.0)	(71.6)	(85.1)	(86.4)

FIGURE 3. Cumulative Positive Results vs Stool Number

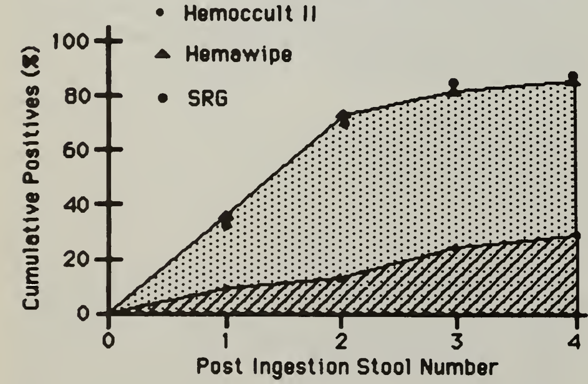

Figure 3

Cumulative positive results as a function of the number of bowel movements after blood ingestion.

Table 5

CUMULATIVE POSITIVE RESULTS VS TIME AFTER INGESTION

Time (Hours)	*12*	*24*	*36*	*48*	*72*	*96+*
	Number (and percent) of positive conversions					
Hemoccult II	6	13	16	19	21	21
(%)	(8.1)	(17.6)	(21.6)	(25.7)	(28.4)	(28.4)
Hemawipe	16	43	52	61	62	63
(%)	(21.6)	(58.1)	(70.3)	(82.4)	(83.8)	(85.1)
SRG	15	35	46	58	64	66
(%)	(20.3)	(47.3)	(62.1)	(78.4)	(86.5)	(89.1)

FIGURE 4. Cumulative Positive Results vs Time Post-Ingestion

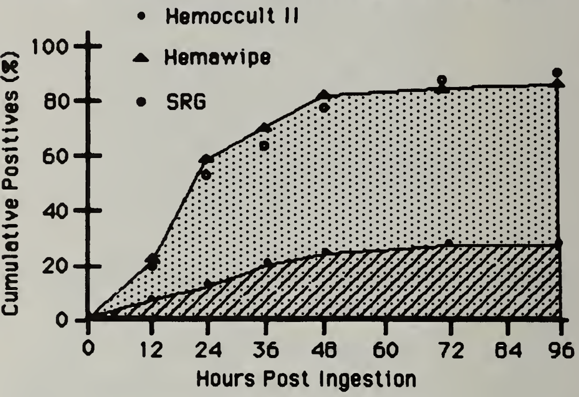

Figure 4

Cumulative positive results as a function of the time after blood ingestion that a stool became positive.

Table 6 shows the results in the patients with verified hemorrhoids. All of the positive samples were associated with the presence of anal fissures or erosions. Table 7 shows the results of the original *in vitro* study. This study was repeated at a later date (Table 8) to confirm the low sensitivity shown by Hemoccult. Table 9 shows the results of the user preference questionnaire.

Table 6

RESULTS IN PATIENTS WITH HEMORRHOIDS

	HEMOCCULT II	*HEMAWIPE*	*SRG*
NEGATIVE	51	48	50
TRACE	1	2	1
1+ or Greater	2	4†	3

† The two subjects showing significant positivity with Hemawipe who were negative with Hemoccult showed physical signs associated with bleeding (fissures and inflammation).

Table 7

IN VITRO SENSITIVITY WITH FRESH HEMOGLOBIN IN SOLID STOOLS AND IN STOOL EMULSIONS

mg Hgb./100g stool (ml blood equivalent)	*HEMOCCULT II* Lot #1128	*HEMAWIPE*	*SRG*
REACTION IN SOLID STOOL SAMPLES			
800 (5.7)	1+	3+	3+
600 (4.3)	0	2+	3+
400 (2.9)	0	TR	TR
200 (1.4)	0	0	0
100 (0.7)	0	0	0
REACTION IN STOOL EMULSIONS			
300 (2.1)	TR	3+	3+
200 (1.4)	0	TR	TR
100 (0.7)	0	0	0

Table 8

IN VITRO SENSITIVITY TO HEMOGLOBIN SOLID STOOLS, STOOL EMULSIONS AND IN AQUEOUS SOLUTION

mg Hgb./100g stool (ml blood equivalent)	*HEMOCCULT II* *Lot #1748*	*Lot #1048*	*HEMAWIPE* *Lot #H4NO14*
REACTION IN SOLID STOOL SAMPLES			
800 (5.7)	1+	0	3+
600 (4.3)	1+	0	3+
400 (2.9)	TR	0	3+
300 (2.1)	0	0	1+
200 (1.4)	0	0	TR
100 (0.7)	0	0	0
REACTION IN STOOL EMULSIONS			
400 (2.9)	3+	1+	3+
300 (2.1)	1+	TR	2+
200 (1.4)	TR	0	1+
100 (0.7)	0	0	TR
REACTION IN AQUEOUS SOLUTION			
Hgb. (mg/dl)			
50	3+	2+	3+
25	2+	1+	3+
10	2+	1+	2+
5	1+	1+	1+
2	TR	TR	TR

Table 9

USER PREFERENCE

Subjects		*Hemawipe*	*Hemoccult II*	*Direct Stool Collection*	*No Preference*
Males	22	18	2	1	1
Females	64	51	5	7	1
Total	86	69	7	8	2

Discussion

Hemawipe is an effective means of obtaining stool specimens for testing for occult blood; of the 407 stool samples collected, only two were considered insufficient. Figure 3 shows that 50% of the volunteers tested passed a stool positive by Hemawipe within 24 hours after the blood ingestion, but some stools remained negative until the fourth day. Hemawipe detected 85.1% of the simulated bleeding episodes; the Hemoccult detection rate was only 28.4%.

The *in vitro* sensitivity of the Hemawipe is close to that suggested as the optimum.[3] It is apparent from the *in-vitro* sensitivity studies that the effect of the stool matrix is profound, and this effect seems to vary with different lots of Hemoccult. This may, in part, account for the relative insensitivity of Hemoccult which has been previously reported.[3,7] In particular, of the three lots tested, Lot #1048 was unable to detect the highest level of fresh hemoglobin in a solid stool sample but was positive with the lowest level of aqueous hemoglobin. This represents a difference in sensitivity of over 400-fold, depending on the mode of testing. In contrast, the two lots of Hemawipe tested were less affected by the stool matrix and showed less lot-to-lot variability. Similar findings have been previously reported,[8,4] and they suggest that sensitivity testing with aqueous solutions or stool emulsions gives an unreliable indication of how the material will actually perform with solid stool samples.

It was difficult for us to find patients with verifiable external hemorrhoids. Although many patients stated that they thought they had them, only about two percent of routinely examined office patients had physical findings. In these patients, only those with tissue breakdown (fissuring, ulceration or inflammation) were positive; the use of the Hemawipe did not aggravate hemorrhoidal bleeding.

Sampling variation presents a difficult problem when evaluating results from specimens obtained by the patient. Since each stool may represent as much as 24 hours or more of gastrointestinal history, isolated bleeding events may be associated only with discrete locations on or in the stool, and these may be missed if spot samples are taken. It has been suggested that the entire stool be homogenized prior to testing, but this has many obvious drawbacks. Direct anal stool sampling, however, may provide the equivalent of such a homogenate. In passing through the anus, a small amount of fecal material from the entire surface of the stool is deposited on the anal area, and this is the sample collected by the Hemawipe. During the blood ingestion study, we occasionally found that one or two areas of the sample would be strongly positive on the Hemawipe but negative with the other methods on the same bowel movement. The entire sample would be positive on the subsequent bowel movement. This suggests that a positive area was picked up, which was missed by spot sampling obtained with a stick. If further studies confirm this, Hemawipe's unique sampling method could provide better detection of sporadic gastrointestinal bleeding.

Conclusions

Hemawipe is an effective, esthetically preferable means of collecting stool samples. Its method of direct anal stool sampling showed no tendency to cause bleeding in patients with or without verified hemorrhoids. A survey of all users in the study demonstrated a nine-fold preference for Hemawipe over Hemoccult II, an increased preference which should translate into increased compliance. Hemawipe's direct sampling method may also provide a more sensitive means of detecting intermittent gastrointestinal bleeding, particularly from lesions in the distal portion of the left colon.

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Leading Causes of Physician Malpractice Claims Occurring in Clinics and Physicians' Offices

Top 10 Allegations

May 1982 through June 1984

During a 25-month period ending June 1984, 3,057 of the physician malpractice claims reported to The St. Paul were alleged to have arisen from treatment of patients in clinic or physician offices. The top allegation, failure to diagnose cancer, accounted for over 10 percent of the claims. The 10 leading allegations together account for nearly half of the total number of claims filed during the period. The data at right shows the number of claims by allegation along with the average cost of the claims.

ALLEGATION	NUMBER OF CLAIMS	PERCENT OF CLAIMS	AVERAGE COST
FAILURE TO DIAGNOSE–CANCER	318	10.4%	$60,581
IMPROPER TREATMENT–DRUG SIDE EFFECT	228	7.5	34,318
FAILURE TO DIAGNOSE–FRACTURE OR DISLOCATION	140	4.6	20,947
FAILURE TO DIAGNOSE–PREGNANCY-RELATED PROBLEMS	112	3.7	25,491
SURGERY–POSTOPERATIVE COMPLICATION	112	3.7	18,732
IMPROPER TREATMENT–INCORRECT DRUG	99	3.2	21,604
FAILURE TO DIAGNOSE–INFECTION	85	2.8	46,540
IMPROPER TREATMENT–FRACTURE OR DISLOCATION	81	2.7	17,195
IMPROPER TREATMENT–LACK OF SUPERVISION OR CONTROL	79	2.6	17,980
IMPROPER TREATMENT–INFECTION	77	2.5	19,962
ALL OTHER ALLEGATIONS	1,726	56.5	
TOTAL	3,057	100%	

—*Malpractice Digest*, October 1984

Mood Disorders: Pharmacologic Prevention of Recurrences

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

Mood disorders, also called affective illnesses, are common and serious conditions. It is estimated that at any given time 3 to 4 percent of the nation's population will be suffering from a major depressive or manic episode. Recurrences are frequent. During the past decade, clinical and research interest in mood disorders has expanded beyond the treatment of acute episodes to include consideration of long-term maintenance treatment aimed at preventing or reducing the frequency and intensity of further attacks. This broadening of focus has occurred in the context of improved approaches to the description and classification of these disorders and newer epidemiologic studies. Recent evidence has demonstrated the recurrent and chronic nature of these illnesses and the extent to which they represent a continual source of distress and dysfunction for affected individuals and their families, as well as a substantial burden to society. Interest in preventive maintenance treatment has been stimulated further by results from recent long-term trials involving antidepressant drugs and lithium.

The need to consider the longitudinal nature of affective disorders in treatment planning has raised many issues of concern about whether, when, and how to use psychopharmacologic agents to protect patients against recurring episodes of depression or mania. In an effort to resolve questions surrounding these issues, the National Institutes of Health in conjunction with the National Institute of Mental Health convened a Consensus Development Conference on Mood Disorders: Pharmacologic Prevention of Recurrences on April 24-26, 1984. After a day and a half of presentations by experts in the field, a consensus panel including representatives of psychiatry, psychology, pharmacology, epidemiology, internal medicine, and the general public considered the scientific evidence and agreed on answers to the following key questions:

1. How common are recurrent mood disorders, and what are the variations in the course of these illnesses?
2. What groups of patients with mood disorders should be considered for preventive maintenance medication?
3. How effective are these medications in modifying the course of recurrent affective illness?
4. What principles guide selection of specific therapeutic agents for these groups?
5. What are the treatment strategies for using these medications on a long-term basis? What additional or alternative strategies are available for breakthrough episodes, treatment failures, or aspects of the illness unresponsive to medication?

From the Office of Medical Application of Research, National Institutes of Health, Bethesda, MD.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

6. What are the long-term risks and complications of maintenance therapy? How should these be assessed and managed?
7. What research areas need further development?

Panel's Conclusions

Recurrent mood disorders have high prevalence and serious consequences but are currently underdiagnosed and undertreated. There are groups of patients with recurrent mood disorders for whom treatments are available which effectively reduce the frequency and intensity of subsequent episodes. Complete evaluation and careful differential diagnosis are required before initiating long-term preventive treatment. For patients with bipolar disorders, who are particularly likely to suffer recurrences, extensive studies have supported the efficacy of lithium in preventing recurrences.

While unipolar disorder is associated with a reduced rate of recurrence, both lithium and the tricyclic antidepressants have been shown to be effective as long-term preventive treatments for recurrent unipolar disorder.

Although the long-term use of these agents poses certain risks, they are not appreciably different from their use in acute situations. Applying appropriate strategies to the management and use of these drugs will enhance the likelihood of compliance and consequent prevention of recurrences with a minimum of bothersome side effects. Such strategies must be used within the context of an ongoing, supportive relationship among the doctor, the patient, and the family.

Research priorities should be placed on basic research aimed at elucidating the etiology and pathogenesis of major mood disorders and the development of more effective treatments.

1. How common are recurrent mood disorders, and what are the variations in the course of these illnesses?

Recurrent major mood (affective) disorders are highly prevalent and have serious consequences. These conditions often are not accurately identified by either patients or clinicians and even when correctly diagnosed are often undertreated or not treated at all. Precision in differential diagnosis using explicit inclusion and exclusion criteria is essential to the identification and optimal treatment of these disorders.

"Depression" can refer either to a normal mood or to an illness requiring treatment. The normal mood, which consists of those transitory feelings of sadness or discouragement that everyone experiences during difficult times of life, is not what is being discussed in this report but rather the specific clinical syndromes of depression and mania. Within this clinical context, the symptoms of depression are many and varied. They may include loss of interest or pleasure in almost all usual activities; poor appetite or weight loss or increased appetite or weight gain; insomnia or hypersomnia; psychomotor agitation or retardation; decrease in sexual drive; loss of energy; fatigue; feelings of worthlessness, self-reproach, or excessive or inappropriate guilt; difficulty thinking or concentrating; and, most serious, suicidal thinking or attempts. Some individuals with manic syndromes may be euphoric, over-confident, and optimistic. However, their mood is typically brittle and deteriorates rapidly into irritability. Others may only be angry or irritable. These individuals may become more active, restless, and talkative; feel that their thoughts are racing; have an inflated sense of self-esteem; be distracted easily; and engage impulsively in activities that could have severe consequences, such as buying sprees, sexual indiscretions, violent behaviors, or foolish business investments. As a result, mania can be devastating to personal relationships and careers.

For the purposes of this report, a major recurrent mood disorder represents a full-blown syndrome of depression or mania, as defined by criteria set forth in the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition (DMS-III).* Other affective disorders, such as single episodes of depression, chronic milder depression of at least 2 years' duration (dysthymic disorder), and mild depressive or hypomanic syndromes, are discussed only when they occur in patients who also have a recurrent major mood disorder. These other affective disorders also should be recognized as important causes of emotional impairment and often will benefit from treatment, but they are beyond the scope of this consensus statement. Depressive and manic states caused by medical disorders (e.g., hypothyroidism) or exogenous, agents (e.g., amphetamines) also are not considered.

The division of major mood disorders into *unipolar* and *bipolar* subtypes is clinically useful. Patients with unipolar disorder have episodes of depression only; patients with bipolar disorder have either episodes of mania or hypomania and depression or episodes of mania alone. Unipolar disorder is reported to be considerably more prevalent than bipolar disorder. Family and genetic (twin, adoption, and pedigree) studies provide compelling support for strong heritability of these disorders, especially bipolar disorder.

The rates of recurrence, variations in course of illness, and results of clinical trials in this report are based on studies involving patients who sought treatment at inpatient and outpatient units affiliated with university medical centers. It is premature to generalize from these data on course and outcome for the entire population of persons with recurrent mood disorders, which presumably includes a substantial number whose conditions remit spontaneously, who never seek treatment, or who are treated in other settings. However, the treatment recommendations derived from these studies are applicable to patients who suffer major recurrent mood disorders regardless of the setting in which they are seen.

Variations in Patterns of Course of Illness

Relapse refers to the exacerbation of an ongoing episode after an initial suppression of symptoms. *Recurrence* refers to a new episode that follows a complete recovery that has lasted for at least several months. Treatment for preventing a relapse is called *continuation therapy* and is distinguished from longer term efforts to prevent completely or reduce the intensity and frequency of recurrence *(preventive treatment).* Thus, the sequence of treatment may be: (a) an acute phase to control disabling symptoms (may be measured in weeks), (b) a continuation phase to avoid relapses of a single episode (may be measured in months), and (c) a preventive phase to avoid recurrences of new episodes over time (may be measured in years). This report addresses only the third item in the sequence—the preventive treatment of recurrent episodes of affective disorders.

Most of the information presented in this section on course of illness is based on the study of patients whose treatment was not under the control of research investigators, and a substantial proportion of these patients received either minimal or no treatment.

Most patients who have a manic episode go on to have a course marked by multiple recurrences of major depressive and manic episodes. The course of unipolar depression is more variable and less well established. Studies suggest that between 50 and 85 percent of patients with a major depressive episode who seek treatment at university medical centers will have at least one subsequent episode of depression in their lifetime. Between 10 and 15 percent of unipolar patients will have subsequent episodes that will involve manic or hypomanic symptoms, at which point they are reclassified as having a bipolar disorder. This reclassification occurs less frequently as patients become older and have an increased number of depressive episodes.

Although there are fewer studies of affective disorder in children and adolescents than in adult populations, emerging evidence suggests that these disorders *do occur* in childhood and, when present, may have a chronic, recurring course. It is reported that the lifetime incidence of major depression is as high as 30 percent by late adolescence in children who have at least one parent with a major affective illness.

Once mood disorders become recurrent, they have a course marked by high rates of relapse and recurrence and significant morbidity in subsequent episodes and in the intervals between episodes.

Fifteen to 20 percent of patients with a recurrent unipolar disorder do not recover fully from any given episode and have persistent symptoms for at least 2 years. Recently, similar rates have been reported for patients with bipolar disorder who formerly were believed to have much higher rates of full recovery between episodes.

As many as 50 percent of patients with recurrent unipolar disorders who recover from a given episode are reported to have a recurrence within the first 2 years after recovery. The likelihood of recurrence is greatest in the 4 to 6 months following initial symptomatic recovery; this risk levels off markedly between 6 and 12 months and is still lower after the patient has been well for 18 months. Some evidence suggests that the length of well intervals between episodes decreases for the first few episodes and then remains steady, while the duration of episodes remains fairly constant. The rate of recurrence in bipolar patients is greater than in unipolar conditions and does not decrease over time.

Some recurrent affective disorders have courses of illness marked by discrete episodes with minimal or no symptoms or impairment in social functioning in the intervals between episodes. Other patients have more insidious onsets of episodes, as well as less complete symptomatic recovery and more impairment in social functioning in the intervals between episodes. The proportion of patients in each of these groups is unknown. Patients who have either of these patterns also may have antecedent or concurrent nonaffective mental disorders.

Factors That Increase Risk of Recurrence

A substantial proportion of patients with recurrent mood disorders also suffer from a dysthymic disorder. If dysthymic symptoms persist after recovery from the major depressive syndrome, the risk of developing new episodes of major depression is especially high. The presence of a nonaffective psychiatric disorder such as alcoholism, drug dependence, or anxiety disorder and an older age of onset also substantially increase the risk of recurrence in unipolar or bipolar recurrent disorders. In addition, the greater the number of previous episodes, the higher the risk of recurrence.

Health and Social Consequences

Complications of affective disorders include attempted and completed suicide, increase in deaths from nonpsychiatric medical causes and accidents, impaired social functioning, impaired occupational functioning, impaired parenting, and marital discord. The rates of these events and their severity are substantial.

2. What groups of patients with mood disorders should be considered for preventive maintenance medication?

Before preventive medication is begun, the patient should have a careful medical evaluation to search for organic cause(s) of the affective syndrome or conditions that would contraindicate the use of one or another of the proposed treatments. A comprehensive medical history, physical examination, and appropriate laboratory tests are indicated. This evaluation should include an assessment by, or consultation with, a clinician skilled in the differential diagnosis of mental disorders.

Bipolar Disorder

Patients who have a manic episode are at high risk for recurrences. Manic episodes themselves are very disruptive. The likelihood of becoming psychotic (i.e., having delusions or hallucinations) when manic or depressed is great, and suicide risk is high. Therefore, the occurrence of a manic episode should *always* raise the question of preventive therapy.

Patients who have not had a full-blown manic episode, but have had a hypomanic and a depressive episode, are also at high risk for recurrence and are more likely to become psychotic when depressed than are patients with unipolar disorder. Therefore, careful consideration should be given to implementing preventive therapy in these patients. Other factors in this patient group that indicate a need to consider preventive therapy include number and recency of prior episodes of depression, family history of bipolar disorder, past suicide attempts, past psychotic episodes, past functional incapacity associated with episodes, and level of social functioning or affective symptoms between episodes. Each of these factors tends either to increase the likelihood of recurrence or to be associated with considerable disability and risk should a new episode occur.

Unipolar Disorder

This condition is less frequently recurrent than the bipolar disorders, and the efficacy of the preventive treatments is less clearly established. Therefore, the decision of whether and when to initiate preventive therapy is more highly individualized for patients with unipolar disorders. It depends on identifying those unipolar patients with a high risk of recurrence. The presence of another mental disorder, a chronic medical disorder, or chronic affective symptoms each increases the rate of recurrence, as does older age at the onset of the first depressive episode. Psychotic features, serious suicide attempts, or serious functional impairment during recent episodes all predict increased severity in subsequent episodes. A family history of suicide, bipolar disorder, or psychotic affective episodes also is predictive of increased severity.

Additional Considerations

Additional factors also play a role in the timing and decision to begin preventive therapy in patients who have never had a manic episode. A slow or incomplete response to treatment for a prior episode of depression would lead one to consider preventive therapy more closely. A rapid therapeutic response in a patient with long intervals between episodes argues against the initiation of preventive therapy. The potentially irreparable disruption that a depressive episode may exact on a patient's work, family, and social relationships also would increase the need for preventive therapy. The decision to use preventive treatment is complicated in women who are, or may become, pregnant. Special consideration is also needed for patients who find the presence of side effects disruptive or highly unpleasant. For such patients the decision involves the careful weighing of the potential benefits and risks of preventive treatment.

3. How effective are these medications in modifying the course of recurrent affective illness?

Bipolar Disorder

In a summary of 14 studies of bipolar disorder, the percentage of patients having a recurrent episode of either mania or depression during 1 year after the start of treatment was greatly reduced by lithium maintenance in contrast to placebo. In most of these studies, the number of recurrences was reduced by 50 percent compared to placebo, and the recurrences were less severe. However, rapidly cycling bipolar patients, i.e., those who have three or more episodes a year, often respond poorly.

Preventive treatment with lithium is equally effective against both manic and depressive recurrences in male and female bipolar patients of all ages from early adulthood to old age, but few data are available for children and adolescents and for the elderly.

The preventive effect of lithium may not develop fully for several months. An early recurrence of bipolar illness following initiation of treatment should not necessarily lead to its abandonment. Antidepressants have not been shown to be effective in preventing recurrence of manic episodes in bipolar disorder.

Unipolar Disorder

Many controlled studies have shown that preventive treatment with lithium or antidepressants (imipramine and amitriptyline) can substantially prevent recurrent episodes of unipolar depression. In most patients, lithium and tricyclics decrease the frequency and/or intensity of recurrences. In six studies with follow-up periods ranging from 5 months to 3 years, the percentages of patients who relapsed or had a recurrence on placebo were significantly greater than the percentages of patients who relapsed or had a recurrence on lithium. In a similar manner, a significant difference between tricyclic antidepressants and placebo was found in several studies. Most studies, however, find lithium and tricyclics to be equally effective or lithium to be somewhat superior.

Individual patients may respond better to either lithium or tricyclics. One multicenter study suggests that patients whose last episode was severe have a better response to imipramine and that patients whose last episode was of only moderate intensity respond equally well to lithium and tricyclics. Research to date has not produced clear-cut guidelines for choosing one over the other when all other factors are equal, nor has it supported the combination of the two as superior to either alone.

Tricyclic antidepressants and lithium prevent recurrences of unipolar depression in both men and women of all ages from early adulthood to old age; however, few data are available for children and adolescents and for the elderly.

Successful prevention of recurrence may involve other important gains, including increased stability of mood during intervals between episodes, regained self-esteem, renewed hope for the future, improved social relations, enhanced vocational abilities, and increased enjoyment of recreational activities.

Because the preventive treatment of recurrent mood disorders is clearly effective for large numbers of persons suffering from these conditions, and because a substantial proportion do not now seek treatment or are not accurately diagnosed, systematic efforts should be made to bring about a greater awareness and understanding by both health professionals and the public of the nature and effective treatment of these illnesses.

4. What principles guide selection of specific therapeutic agents for these groups?

Decision to Initiate Preventive Treatment

Repeated and candid discussions with the patient and the patient's spouse or other relatives are mandatory to ensure full understanding of potential advantages and risks of preventive treatment *as well as of no treatment.* These discussions should begin as early as possible after an acute episode is under control. The clinician should have complete information regarding the illness from the patient's and the family's perspective, and it is essential that patients and their families share in the decision-making process. The possible salutary effects on family and job stability should be explained thoroughly, and the known serious and troublesome side effects of each drug under consideration should be made clear. The necessity and importance of long-term monitoring, including required laboratory tests, should be understood fully. Compliance during treatment is improved greatly when all parties understand the therapeutic goals.

Choice of Drugs

Lithium is the drug of choice for preventing recurrences of bipolar disorder. In treating unipolar disorders, both lithium and tricyclic antidepressants have been shown to be effective for prevention. Since most patients will have been treated previously with tricyclic drugs for their depressive episodes, it is usually most appropriate to continue with the same drug, provided it has been effective and is well tolerated. Tricyclic antidepressants also may be preferable in older patients in whom renal function shows a normal decline with age. In addition, elderly individuals are more likely to be using other drugs to treat concurrent illnesses. Either these other agents or the illnesses themselves could interfere with lithium excretion and, thereby, predispose to toxicity. On the other hand, some older patients may be more vulnerable to certain side effects of the tricyclic antidepressants, such as urinary retention, cardiac arrhythmias, and increased intra-ocular pressure. Some clinicians recommend that lithium be used in both bipolar and unipolar cases to minimize the risk of an unexpected manic episode in a patient considered to be unipolar. In particular, lithium may be preferable for patients who have first degree relatives with a history of bipolar illness or whose psychiatric history is uncertain, since some previously diagnosed unipolar depressions ultimately may prove to be bipolar. The consequences of an unexpected manic episode, which lithium is likely to prevent, are generally serious.

Only a few tricyclic antidepressants have been used in controlled studies of the preventive effect of these agent. It is likely, however, that all standard tricyclic drugs are equally effective, although the question has not been studied empirically. On the other hand, some patients seem to respond to one tricyclic antidepressant after receiving no benefit from another, and side effects will differ from patient to patient and agent to agent. Thus, close monitoring is required, and some sequential courses of treatment with different antidepressants may be indicated.

5. What are the treatment strategies for using these medications on a long-term basis? What additional or alternative strategies are available for breakthrough episodes, treatment failures, or aspects of the illness unresponsive to medication?

Use of Lithium and Tricyclic Antidepressants

Specific clinical guidelines for the use of lithium and tricyclic antidepressants are available in various pharmacologic and psychiatric textbooks as well as articles in professional journals. Unfortunately, despite the interest in various biological tests for the diagnosis and treatment of mood disorders (dexamethasone suppression test, thyrotropin releasing hormone test, thyroid stimulating hormone test, measurement of 3-methoxy-4-hydroxyphenethyleneglycol), no clear-cut guidelines for their use in the treatment of recurrent mood disorders have been established. What follows is only a brief outline of the use of these drugs as preventive agents.

Preventive doses of tricyclic antidepressants have not been adequately defined and, thus, physicians must be flexible in seeking to achieve optimal control. In general, doses similar to or somewhat lower than those used in treating the acute episode have been found effective. Studies of long-term preventive maintenance treatment with tricyclics have not adequately evaluated the effectiveness of dosages greater than 150 mg/day. Lithium in conventional forms is satisfactory. The goal in lithium treatment is to achieve serum concentrations between 0.6 and 0.8 mEq/L in most patients. While some patients may require higher concentrations, in general the physician is advised to maintain the patient on the lowest dose that prevents the return of symptoms since these lower concentrations are associated with fewer side effects.

Duration of Treatment

Duration of treatment must be determined on an individual basis, depending on the previous pattern of episodes, degree of impairment produced, the adverse consequences of a new recurrence, and the patient's ability to tolerate the drug. Data concerning the optimal duration of treatment are lacking. Most clinicians, as well as patients, would be loath to embark on a lifetime course of treatment. If the patient remains free of recurrences during a period equivalent to several of the previous cycle lengths, a decision may be reached to discontinue treatment, provided that a family member or friend of the patient is available to alert the patient and, if necessary, the physician to symptoms of recurrence. In general, the stronger the indications for initiating preventive treatment, the longer its duration should be.

When tricyclics are discontinued after long-term exposure to the drug, the process should be gradual to avoid symptoms that sometimes occur after sudden cessation. Thus, decreases in doses may be spread over weeks or months, with larger decrements early in the withdrawal phase and smaller decrements once the daily dose becomes 50 mg or less. Discontinuation of lithium can be done abruptly or spread out over a couple of weeks. The latter is probably advisable for patients receiving relatively high doses. Neither drug is addictive or prone to abuse.

Breakthrough Episodes

Breakthrough episodes during preventive treatment are manifested by the emergence of clinically significant signs and symptoms of either mania or depression. Purely symptomatic treatment (e.g., sedative hypnotics or anxiolytics) should be delayed at this stage since close assessment over several weeks is desirable to be sure that a clinically significant recurrence of symptoms has occurred. When such breakthrough occur during lithium treatment, the first step is to check serum lithium levels either to assure compliance or to justify an increased dose. The second step is to check the thyroid status, since hypothyroidism may mimic depression. The third step would be to add to the lithium an antipsychotic for manic breakthroughs or an antidepressant for depressive breakthroughs. These agents, however, should be used only temporarily for relief of the acute symptoms and should be withdrawn when these symptoms abate.

Treatment Failures

If the aforementioned measures fail, other treatments should be tried. Although many alternatives have been suggested, none has been extensively tested. Several reasonable alternatives are the replacement of lithium with carbamazepine, the addition of carbamazepine to lithium, or the replacement of tricyclic antidepressants with monoamine oxidase inhibitors for depressive treatment failures. Electroconvulsive therapy may also be considered for either manic or depressive treatment failures, particularly where suicidal risks seem high.

Some patients, usually those who have frequent and severe recurrences of depression that require large doses of tricyclic antidepressants, may experience more frequent episodes after use of these agents. When such a pattern is recognized, the minimal effective doses of tricyclic should be used. In some cases, allowing a depressive episode to run its course without antidepressant treatment will break the cycle.

Psychological Management of Patients in Preventive Therapy

The problem of patient compliance, especially with lithium, has been well documented in several studies. Medication side effects as well as patient and family attitudes toward these illnesses and their treatment may each contribute to noncompliance. It is believed that the treating physician can make a considerable impact on treatment efficacy by counseling patients who are on preventive therapy, interviewing carefully, asking directly about particular side effects, eliciting patients' concerns, treating side effects as indicated, and providing information to ensure optimal adherence.

More specific psychotherapies or brief counseling sessions may be helpful in reducing the secondary consequences of chronic conditions that are often associated with recurrent major affective illness (e.g., occupational or marital disruptions). This treatment may be provided either by the treating physician or by another professional skilled in such services.

Three types of psychotherapy (cognitive, interpersonal, and behavioral) have been found helpful in alleviating depressive symptoms. Whether these specific psychoterapies or others also play an adjuctive role with pharmacotherapy in preventing recurrence has not been firmly established. Based on our present state of knowledge, for nearly all patients suffering from major recurrent mood disorders, psychotherapy should be used in combination with, not as a substitute for, pharmacotherapy for long-term preventive treatment.

6. What are the long-term risks and complications of preventive therapy? How should these be assessed and managed?

Adverse Effects of Preventive Treatment

The risks of preventive therapy with lithium or tricyclic antidepressants do not appear to differ appreciably from the adverse reactions to these drugs for treatment of acute episodes of mood disorders, with the exception of impaired thyroid function, which may increase in frequency over time on preventive lithium therapy. Because lower doses are frequently successful for prevention, side effects may, in fact, be less of a problem. The earlier fears of irreversible renal damage now seem to be unwarranted. Except during the first trimester of pregnancy, there are few significant permanent risks with either lithium or tricyclic therapy. There may be minor renal tubular defects and hypothyroidism brought on by long-term lithium therapy, and a few patients may be at minimal risk for arrhythmias with extended treatment with tricyclic antidepressants. Tricyclics may lead to weight gain, orthostatic hypotension, subtle confusional states, and exacerbation or mania. Lithium may create symptoms of thirst, polyuria, tremor, diarrhea, weight gain, or, less commonly, hypothyroidism. Memory problems, tiredness, and a dulling of senses have been reported as additional complications of lithium that may contribute to noncompliance. Separation of these possible side effects from symptoms of the illness needs to be explored. A carefully supervised reduction in dose, reevaluation of thyroid status, or a therapeutic trial of antidepressants are ways in which the distinction may be achieved. Because patients with mania and depression are at high risk for suicide, supplies of medication should be limited. Adverse consequences of lithium on the fetus and nursing newborn should be made known to women who may become pregnant. Preventive use of lithium and tricyclic antidepressants in children and adolescents must be based on clinical judgment, as risks and benefits have yet to be firmly established. Preliminary studies suggest that the potential problems are similar to those seen in adults.

Monitoring for Adverse Effects

Follow-up visits at regular intervals provide an opportunity to assess changes in clinical status, resolve compliance issues, institute appropriate medical interventions, and establish a basis for treatment during breakthrough episodes. More frequent contact is clearly necessary during periods of potential recurrence or change in clinical status. Clinical observation and laboratory tests provide useful benchmarks in the event of complications during long-term treatment. Current practice during treatment with lithium is to monitor serum lithium levels at intervals of 1 to 3 months and to assess serum creatinine values and thyroid stimulating hormone (TSH) values every 6 to 12 months. Additional studies such as EKGs may be needed to elucidate other adverse effects.

Lithium intoxication is less likely in patients on low doses and with low serum concentrations as recommended here for preventive treatment. Patients should be advised always to keep well hydrated and to report immediately intercurrent illnesses that cause vomiting, diarrhea, or fever, or treatment with or use of new drugs.

7. What research areas need further development?

There are many deficiencies in our knowledge of how best to prevent recurrent mood disorders.

The fundamental questions that underlie these deficiencies and need to be investigated are:

1. Why do some patients develope severe recurrent illnesses while others do not?
2. Why do some patients respond well to preventive treatment while others do not?
3. Why do some patients lose benefits after an initial response to treatment?

Answers to these questions will require information from therapeutic, epidemiologic, neurobiologic, and genetic studies. The results of such studies should elucidate basic mechanisms of the disorders themselves.

Some research strategies would include, for example, studies of high-risk populations (e.g., children of a parent with a mood disorder), the development and testing of new therapeutic approaches, and identification of clinical and biochemical predictors of recurrence. The panel feels that priority should be given to the search for new knowledge about the pathogenesis of mood disorders. Such knowledge might then lead to new and more effective therapies for their treatment.

Members of the Consensus Development Panel were: David J. Kupfer, M.D., (Chair), Pittsburgh, PA; Philip A. Berger, M.D., Stanford, CA; John Janeway Conger, Ph.D., Denver, CO; Jean Endicott, Ph.D., New York, NY; John A. Gergen, M.D., Frankfort, KY; Samuel B. Guze, M.D., St. Louis, MO; Leo E. Hollister, M.D., Palo Alto, CA; Martin B. Keller, M.D., Boston, MA; Eugene M. Laska, Ph.D., New York, NY; Roderick E. Prior, M.D., Farmington, ME; Hilda H. Robbins, B.S., Fort Washington, PA; A. John Rush, M.D., Dallas, TX; Lisbeth B. Schorr, Washington, DC.

Members of the Planning Committee were the following: Robert Prien, Ph.D., (Chair), Rockville, MD; Paula J. Clayton, M.D., Minneapolis, MN; Frederick K. Goodwin, M.D., Bethesda, MD; Robert M.A. Hirschfeld, M.D., Rockville, MD; David J. Kupfer, M.D., (Chair), Pittsburgh, PA; Fitzhugh Mullan, M.D., Bethesda, MD; Harold Alan Pincus, M.D., Rockville, MD; Frederic M. Quitkin, M.D., D.M.Sc., New York, NY; Margaret C. McDonald, Pittsburgh, PA.

The conference was sponsored by the following: National Institute of Mental Health, Larry B. Silver, M.D., Acting Director; Office of Medical Applications of Research, Itzhak Jacoby, Ph.D., Acting Director.

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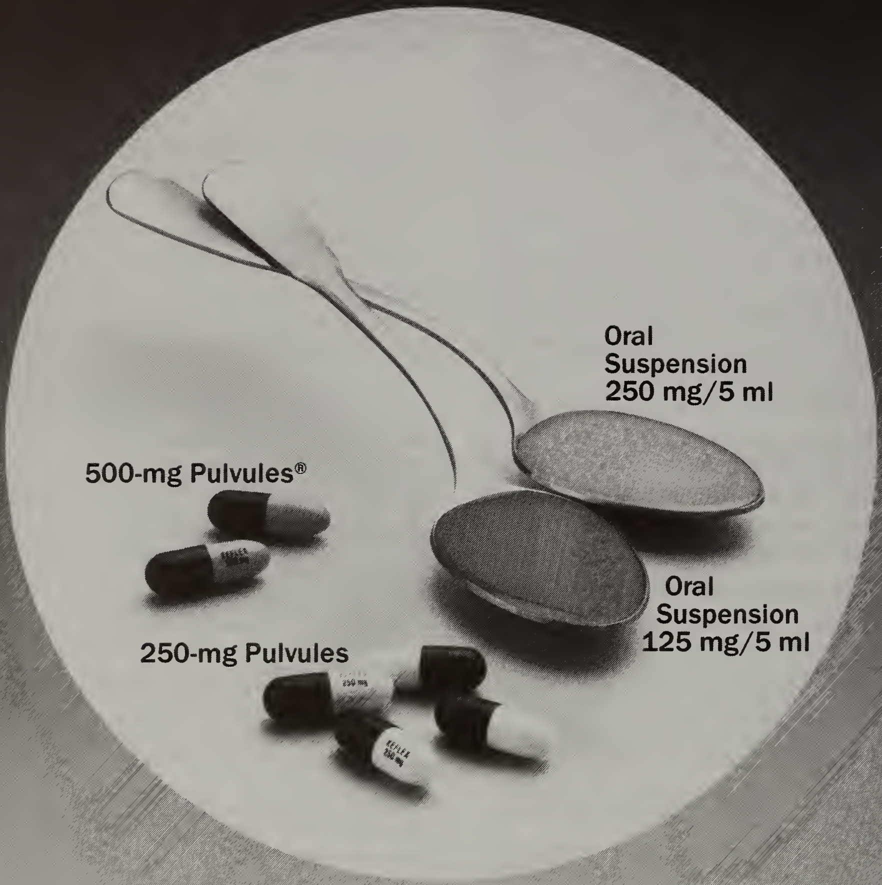

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The Living Will

SENATOR WILLIAM F. ROGERS, III

Connecticut's State Lottery required seven attempts in the Legislature before being enacted. With that example, a law to legalize a living will would have to be introduced twice more.

When I was first elected to the State House of Representatives in 1979, I introduced a bill entitled "An Act concerning a Right to a Natural Death." Also known as "Death With Dignity." The bill was referred to the Public Health Committee, then chaired by two strong Pro Lifers, Senator Regina Smith and Representative Paul La Rose. The bill was killed in Committee, incorrectly being equated with abortion and/or euthanasia by the chairmen.

Under the strong urging by many House members, I petitioned the bill out of committee with signatures from 78 House members of the total of 151 there. In an impassioned plea by Representative York Allen of New Canaan, the "unfavorable" report of the committee was overturned and the legislation was passed and sent along to the Senate. At that time, the Pro Life groups in the state had not joined forces to any extent with the Roman Catholic hierarchy in opposing such a bill.

The bill then languished on the calendar of the Senate until the day before adjournment. As in the House, the first order of business of the Senate would be the acceptance of the House Committee's unfavorable report. The vote was 20 to 16. But Senator Nancy Johnson, now Congressman from New Britain for the 6th Congressional District, suddenly realized she had cast her vote incorrectly, desiring to reject the unfavorable report. Having been on the prevailing side of the vote, she was entitled by Parliamentary Rule to request reconsideration of the vote, which she did. On the vote to reconsider, the result was a tie, 18 to 18; the motion to reconsider in the Senate had failed. However, to deliver the coup de grace, the chairman, now Governor William O'Neill, gavelled it dead with his tie breaking vote "no."

The bill was not introduced in 1980, a year reserved for fiscal matters only, unless introduced as a Committee bill. (The Public Health Committee is made up of members from both the House and the Senate, and since it had been killed in committee in 1979 there was no hope that it would be approved and presented to the House for vote.)

In 1981, I had been elected to the Senate. Considerable changes had come about in the Senate makeup. A more liberal body had been elected and there was now overwhelming support for a Living Will. With increased urging by my constituents as well as by such groups as the American Association of Retired Persons, and the United Church of Christ, I again introduced the bill. By then, the Senate Chairman of the Judiciary Committee, Howard Owens of Bridgeport, was interested in the legislation. With no chance for success in the Public Health Committee, he offered his own Committee as a vehicle for the bill's introduction. With Owens' backing and leadership, the bill was passed in the Senate by large majorities in 1981, 1982, 1983, and 1984. However, the House each time continued to reject it, with strong opposition and lobbying by the Connecticut Catholic Conference and Pro Life groups. Both of these continue to shout "euthanasia" and draw the similarity to abortion.

It is interesting to note that the opposition in the House has been decreasing each year. However, in 1984 the lobbying to defeat the bill became intense, and even included intimidation of some House members by some parish priests.

Meanwhile, out in the rest of the country, by the spring of 1984, a total of 21 states had adopted such legislation, California having been the first. In New England only Vermont has passed such a statute.

In 1984, in the House, the fight for such legislation was led by Representative Jamie McLaughlin, an admitted practicing Catholic strongly in favor of the Right to Die philosophy and also Pro Choice on the abortion issue. He came to within three votes of passage, with 73 noes and 70 yeses. Interestingly, eight members took "walks"and thus avoided having to vote on the issue.

During the last several years, I have been strongly

STATE SENATOR WILLIAM F. ROGERS, III, Assistant Republican Leader, Thirty-Second District, Southbury, CT.

EDITOR'S NOTE: A copy of a Living Will may be obtained from the office of CSMS, 160 St. Ronan Street, New Haven, CT 06511.

assisted in my efforts by John J. Paris, SJ, a Jesuit priest from Holy Cross in Worcester, Massachusetts. Father Paris has now become a nationally famous spokesman for his participation in court cases defending the right of doctors and of hospitals, following the desires of the next of kin, to "pull the plug" on terminally ill patients where death is imminent and there is no hope for the patient's recovery. As Father Paris stated in June 20, 1984, in a speech to the Connecticut Hospital Association in New Haven, "Most doctors refuse to shut off life-support machines even though they believe that it is morally, medically, and religiously acceptable to do so." He said they take this position for a single reason—they are afraid of being sued. He points out that, under Living Will statutes on a state's books, not only will the doctor, the hospital or nursing home be protected, but the patient's expressed wishes will be followed.*

Right to Die legislation is strictly voluntary and permissive, no individual's desires should be circumvented by certain beliefs of others. And as the question is now being asked—"Whose Life Is It, Anyway?"

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*Father Paris' speech to the Connecticut Hospital Association was published in *Connecticut Medicine* last month (February, 1985, pp. 105-111).

Connecticut's New Brain Death Law

At the recommendation of the Society's Judicial Committee, we publish Public Act No. 84-261 below. The law was passed in 1984 after several years of legislative efforts by the CSMS.

The accepted standard for determining death has been the permanent absence of respiration and circulation. Advances in medical technology now permit physicians to generate breathing and heart beat when the capacity to breathe spontaneously has been irretrievably lost. Such artifically maintained bodies present a new category for the law (and for society), to which the application of traditional means for determining death is neither clear nor fully satisfactory.

Whether by judicial or legislative means, brain death criteria are being used with increased frequency in the United States for the legal determination of death. During the last two years, thirty-three other states plus the District of Columbia have adopted the Uniform Determination of Death Act.

Public Act No. 84-261

AN ACT CONCERNING THE DEFINITION OF DEATH AND LIFE SUPPORT SYSTEM.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. For purposes of making a determination concerning the continuation or removal of any life support system in a general hospital licensed under section 19a-491 of the general statutes, an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. Determination of death shall be made in accordance with accepted medical standards.

Section 2. For the purpose of this act, "life support system" means any mechanical or electronic device utilized by any medical facility in order to replace, assist or supplement the function of any human vital organ or combination of organs.

The Physician and the Dying Patient: Judicial Council

CONNECTICUT AMA DELEGATION

Introduction

The Connecticut Delegation to the AMA House of Delegates introduced Resolution 11 "Patients Right to Die in Dignity" in the House at its June 1973 meeting. The House referred the Resolution to the Judicial Council "for report back at the 1973 Clinical Convention."

Resolution 11 contained a "background statement" and a resolved clause that asked approval of the following statement:

> TO MY FAMILY, MY PHYSICIAN
> MY CLERGYMAN, MY LAWYER–
>
> If the time comes when I can no longer actively take part in decisions for my own future, I wish this statement to stand as the testament of my wishes. If there is no reasonable expectation of my recovery from physicial or mental and spiritual disability, I, ________________________, request that I be allowed to die and not be kept alive by artificial means or heroic measures. I ask also that drugs be mercifully administered to me for terminal suffering even if in relieving pain they may hasten the moment of death. I value life and the dignity of life, so that I am not asking that my life be directly taken, but that my dying not be unreasonably prolonged nor the dignity of life be destroyed. This request is made, after careful reflection, while I am in good health and spirits. Although this document is not legally binding, you who care for me will, I hope, feel morally bound to take it into account. I recognize that it places a heavy burden of responsibility upon you, and it is with the intention of sharing this responsibility that this statement is made.
>
> ________________________
> Signature
>
> ________________________
> Witness-Date

This statement was approved by the House of Delegates of the Connecticut State Medical Society on April 24, 1973.

In February, 1973, the House of Delegates of the Medical Society of the State of New York approved the following statement:

> "The use of euthanasia is not in the province of the physician. The right to die with dignity, or the cessation of the employment of extraordinary means to prolong life of the body when there is irrefutable evidence that biological death is inevitable, is the decision of the patient and/or the immediate family with the approval of the family physician."

A member of the Association sent the Council the form he had drafted to express his wishes. Because it is simple and nonlegalistic the Council repeats it.

> TO MY FAMILY, TO MY PHYSICIAN–
>
> Should the occasion arise in my lifetime when death is imminent and a decision is to be made about the nature and the extent of the care to be given to me and I am not able at that time to express my desires, let this statement serve to express my deep, sincere and considered wish and hope that my physician will administer to me simple, ordinary medical treatment. I ask that he not administer heroic, extraordinary, expensive or useless medical care or treatment which in the final analysis will merely delay, not change, the ultimate outcome of my terminal condition.
>
> ________________________
> Signature
>
> ________________________
> Date

In addition to the adoption of policy statements, medical societies and medical journals have encouraged discussion of terminal medical care and the wishes of the dying patient in respect to that care. Ethicians, philosophers, theologians and other outside the profession of medicine have actively written about and discussed this subject. Legislation has been introduced in state legislatures regarding the "right of an individual to refuse medical or surgical means or procedures

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Adopted by the AMA House of Delegates, December, 1973.

calculated to prolong his life" and "relating to the right to die with dignity."

The Judicial Council, by way of introduction, cannot help but observe that while it seems that there is a consensus and agreement in regard to the concept, there is considerable difficulty in expressing in words what the consensus or agreement is. Illustrative of semantics involved is the confusion between *euthanasia* and *death with dignity;* and the lack of understanding or agreement about their different connotations.

Survey

The Council asked each state medical association if it had policy on the subject and invited comment on Resolution II.

The Council forwarded copies of the Resolution to each of its Consultants (and is gratified with their wholehearted and extremely valuable cooperation.)

Letter on the subject of "euthanasia and death with dignity" were sent to Churches in the United States whose combined memberships include over 50% of the population. The replies received from all three groups were helpful to the Council.

It reviewed a mass of literature in scientific and nonscientific journals. AM NEWS, AMAGrams and the Green Sheet solicited comments from the members on the subject of medical care for the dying patient. The member-response was gratifying.

Findings

In addition to the statement of the Connecticut State Medical Society, the Euthanasia Educational Council has drafted and widely distributed "A Living Will." The Oregon Medical Association has prepared and distributed, in connection with the state's anatomical gift act, a wallet sized card, which is called "a living will."

There is little sentiment in favor of euthanasia, that is, the direct, intentional, voluntary termination of life.

There is a consensus that, although a physician must decide which treatment is indicated and which is not, the patient needs to agree when the options are explained to him.

There is a consensus that insofar as it is possible a patient's wishes regarding care in terminal illness should be respected.

There is a consensus that, insofar as possible, patients should not be discouraged from indicating, in writing, their wishes regarding refusal of medical treatment during terminal illness; and these wishes should be respected, insofar as possible, even after patients are no longer able to participate actively in decisions about their medical treatment in their last illness.

In some discussions of the right of patient to refuse medical care in terminal illness there is a lack of clarity because those discussions fail to relate to terminal illness. A patient well adjusted to kidney dialysis, lives with "a physicial disability from which he will not recover." Amentally retarded infant suffers from "mental disability from which he will not recover." A diabetic is irreversibly ill.

When the individual asks that medical treatment be withheld in some physical disability from which he may not recover, yet will not die if ordinary care is given—what must the physician do? Is the wish of the father-or mother of two, three or four small children to be accorded the same weight as the wish of a great-grandparent under similar medical conditions?

Recommendations

1. The Council recommends that the several state, county and specialty medical societies encourage and promote discussions of the reciprocal rights and duties of physicians and patients-suffering-terminal-illness.
2. The Council recommends that the House not endorse any particular form to express an individual's wishes which relate prospectively to his final illness but recognize that individuals have the right to express such wishes.

   Physicians may, and indeed should, be encouraged to discuss death and terminal illness with patients. Physicians may, and indeed should, respect expressions of patient's wishes regarding medical care during terminal illness but may, and indeed should feel free to question those wishes with patient's competent legal representative or by appropriate judicial proceedings when the circumstances of a particular situation seem to require it.
3. The Council recommends that the House adopt the following statement to serve as a guideline for physicians:

   > The intentional termination of the life of one human being by another—mercy killing—is contrary to that for which the medical profession stands and is contrary to the policy of the American Medical Association.
   >
   > The cessation of the employment of extraordinary means to prolong the life of the body when there is irrefutable evidence that biological death is imminent is the decision of the patient and/or his immediate family. The advice and judgment of the physician should be freely available to the patient and/or his immediate family.

Financial Criteria, Medical Practice, and the Hospital Medical Staff

DONALD P. WILCOX, J.D.

With the combined effects of inflation, medical technological advances, and a leveling or declining of funding sources to purchase an expanding need of access to increasingly sophisticated medical treatment, financial incentives *not* to provide care have arrived. Thus, talk about necessary vs. unnecessary care is rampant. Some suggest that tests and procedures are done for the primary purpose of producing income, or that tests are done in the name of "defensive medicine," rather than because the care is medically necessary. The Federal program of paying hospitals on the basis of "diagnostic related groups" (DRGs) was created to deal in part with this perception of medical practice. It is anticipated that serious attempts will be made to adapt payment for physician services into the DRG mode. In addition to examining the "quality of medical care" being provided, physicians, medical staffs, hospital administrators, and others are both reviewing and being reviewed as to whether or not the procedures and treatment ordered were truly necessary.

The physician is charged with the duty of seeing that the medical diagnosis and treatment provided meet the needs of each patient. This is the physician's first consideration *(Current Opinions of the Judicial Council of the American Medical Association 1984,* paragraph 2.08). Physicians are advised that although they should be conscious of the costs of medical care and not provide or prescribe unnecessary services or ancillary facilities, the physician's primary responsibility is to the patient under his or her care.

Necessary vs. Unnecessary

Hospital medical staffs will more frequently be asked to decide (1) what "necessary care" is, (2) what diagnostic tests are necessary or unnecessary, and (3) what treatment or procedures are needed or are superfluous? Many benchmarks have been offered to determine whether tests are necessary or unnecessary, at least for the purpose of determining whether or not a third party should pay for the services or whether the services should have been performed. Is a test necessary or unnecessary if the results of the tests will only be helpful in 1 out of 100, in 1 out of 1000 cases, or in 1 out of 10,000 cases? In a Washington State case, the Washington Supreme Court held that if in 1 out of 25,000 tests for glaucoma on patients under 40 results would be positive, a jury would be permitted to find that the test should have been performed, even though the medical standards in the community did not provide that such a test should be done for patients under 40 years of age.[1]

Does the answer to the question of whether the test is necessary depend upon the *cost* of each test? That is, if the test costs only $20, should it always be run even when the answer may impact on the diagnosis or treatment of the patient in only 1 out of 100,000 cases? If the test costs $200 or $2000, is the test unnecessary unless the results will help 1 out of 1000 patients? If the test is designed to detect a minor illness or condition as opposed to a life-threatening disease, are the odds changed with respect to a necessary vs. unnecessary decision?

What if the patient is more than 65 years of age? Does the necessary test in some instances then become the unnecessary test. Is there a difference between high quality medical care without financial shortcuts and medical care which is only "necessary" under the financial restraints dictated by a third party? To the extent tests are not ordered for financial reasons, the lack of these test results will make a difference in a few cases. Patients can improve with poor care. Other patients can get worse even with the best care. But as more and more marginally necessary tests are not ordered, at least some patients will suffer.

If a needed test is not done for financial reasons and the patient suffers a grievous harm, what can we anticipate juries will do? When the patient has a poor result for which hundreds of thousands of dollars in damages are claimed, will the physician or hospital be able to justify its decision to discharge a patient or not to perform a test or procedure because of financial considerations? Hospital

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DONALD P. WILCOX, J.D., General Counsel for the Texas Medical Association, Austin, TX.

medical staff utilization review committees face these decisions daily. In the past, juries have not been sympathetic to the argument that something was not done (which would have made a difference in the outcome) because of financial considerations. The realities of the harm to an individual patient overwhelm the broader social concern over controlling medical costs. Yet, the doctor, the medical staff, and the hospital still must face the realities of financial constraints under a DRG reimbursement system.

We can anticipate a larger role for the hospital and the medical staff in reviewing the practice patterns of physicians geared to help assure the hospital's financial survival. The physician's patient profile in the hospital setting will become more and more important as the DRG concept is refined. More and more pressure will be placed upon those physicians whose profiles are, according to the hospital accountant, costing the hospital money. The medical staff will be placed squarely in the middle as the peer review body in the hospital setting. Pressure will be focused on the individual physician whose profile does not fit the proper pattern.

Duty to Patient

Does the patient have the right to informed consent with respect to the decision that care, tests, or procedures will not be offered to him because their cost will not be reimbursed by a third party? Will two standards of treatment be developed—one for the rich and one for the poor, one based upon financial criteria and the other on what is best for the patient whatever the cost?

Professional liability defense attorneys are already predicting that the DRG system will result in greater potential liability for the hospital and for the medical staff because of the financial pressures that both will place on individual physicians.[2] When the hospital places financial criteria above the needs of an individual patient, has the hospital violated its duty to the patient? Does not the medical staff share this same duty? Is the physician's duty to treat the patient dangerously compromised where the strong suggestion has been given that if not corrected his or her overly expensive profiles will require termination of medical staff privileges at the facility?

Third party payors, particularly the Federal government under Medicare's DRG methodology, has shifted the hard individual decisions to the hospital, to its medical staff, and to the individual physicians taking care of their patients. The government can sit back and say,

> "We did not tell the hospital, the physician, or the medical staff to discharge this particular patient. We are just in the reimbursement business. If the hospital and its physicians properly exercise their duties and responsibilities, they will be *fairly* rewarded under our reimbursement process."

Hospitals and physicians may have a different perspective with respect to the fairness of a cost control system. Harmed patients may also question financially based necessary vs. unnecessary care decisions.

Conflict of Interests

Business arrangements have been proposed by experienced hospital attorneys to provide added interest and incentive to hospital medical staff physicians by permitting them to share in the profits generated from prudent medical care provided to patiens. In other words, if the profiles of medical staff physicians are favorable under the DRG reimbursement system, the physicians will receive some of the savings (profits) the hospital enjoys. Not discussed, is the opportunity of physicians to share a joint loss with the hospital should the profiles not be compaired favorably with DRG reimbursement norms. Thus, the physicians' own financial interests are adversely affected where practice profiles do not meet the norms dictated.

Should not the physician disclose to the patient that he or she will share in the hospital's reimbursement "gains" or "losses," depending upon how quickly the patient is able to leave the hospital, if this is the case? How does this financial risk sharing fit into the physician's primary duty to the patient? Why is not the situation involving the physician sharing in the hospital's profit considered a kickback (for not treating) which would be, if not illegal, unethical for the physician to accept? At a minimum, the physician should inform the patient of such a financial arrangement (see generally, paragraph 6.00 of the *"Current Opinions of the Judicial Council of the American Medical Association 1984").*

Challenges for Physicians

Thus, the physician's duty to the patient will continue to be challenged. The physician cannot fully practice his or her profession without privileges at the hospital. The physician must cooperate with the hospital administration, board, and the medical staff in order to maintain staff privileges. The physician is also in competition with other physicians for patients. Without hospital staff privileges the physician's ability to compete and to practice his or her profession fully is compromised severely. Additionally, since the pressure to discharge hospitalized patients will continue to mount, the hospital will have empty beds. Thus, there may be subtle pressure from the administration for physicians to hospitalize patients who only marginally need hospitalization. The hospital's ideal patient will be sick, but not too sick, i.e., one who will recover quickly and aid the hospital and its medical staff in beating the DRG odds. Of course, such a patient will also improve his or her physician's DRG score with the hospital's accountants and; thus, the physician should be able to secure his position on the hospital medical staff.

Patient's Best Interest

The opportunities for problem solving among medical staffs and hospitals will continue. The AMA Section on Hospital Medical Staffs will be busy, as will similar sections being formed by state societies. These are challenging times. These problems will not be easy to resolve. Physicians active on hospital medical staffs must maintain their ethical perspective and continue to focus on the best interests of their patients.

Costs in providing care are important, but not at the sacrifice of quality. The accountants may pay the bills, but they are not licensed to diagnose and treat patients. Physicians individually and hospital medical staffs must not be lured into becoming financial officers first and doctors second. Rather, utilization controls must be used constructively as a statistical tool to aid in the scientific analysis of medical practice patterns so that medical diagnosis and treatment can continue to develop in a positive, patient oriented manner. Positive behavioural charges among physicians "is far more likely if reliable information is coupled with complementary financial and professional incentives."[3] Each physician's stubborn strength is still vital to all of us whose loved ones will one day be ill or injured and be in need of the "best medical care money can buy."

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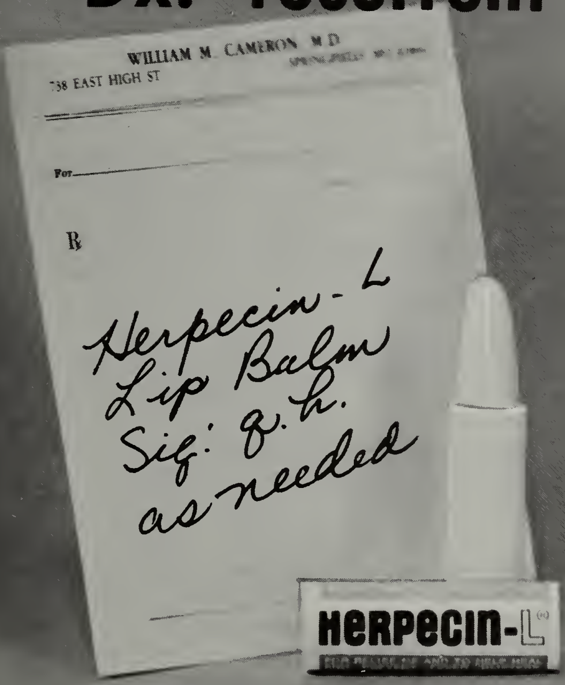

Report of Ad Hoc Commission on Vaccine Injury Compensation

AMA BOARD OF TRUSTEES

Introduction

During the June 1983 Annual Meeting of the AMA House of Delegates, Board of Trustees Report OO, "National Vaccine Injury Compensation Program (Substitute Resolution 9, 1-82)," was adopted. In this report, the Board recommended the convening of a special Ad Hoc Commission "to serve as a forum to examine all aspects of the vaccine injury compensation problem and provide recommendations for any appropriate legislative remedy." Such a Commission was established and members met on two separate occasions: September 12 and November 10, 1983. Commission membership included representatives from the AMA Board of Trustees and Councils on Legislation, Medical Service and Scientific Affairs. Additionally, the following national organizations were represented:

American Academy of Family Physicians
American Academy of Pediatrics
American Society of Internal Medicine
National Medical Association
American Association of Public Health Physicians
Institute of Medicine
National Conference of State Legislatures
Pharmaceutical Manufacturers Association
United States Department of Health and Human Services' Centers for Disease Control.

Four vaccine producers also were invited and sent representatives to the Commission's meetings. These included observers as well as experts in pharmaceutical products liability.

At its first meeting, the Commission received data and presentations on the scientific and legal environment in which vaccine producers and immunization programs now must operate. To address the paramount concerns in the most pressing area, Commissioners agreed to focus on state mandated pediatric immunizations. Out of these deliberations emerged the strong recommendation that all children receive the childhood immunizations recommended by the American Academy of Pediatrics and the American Medical Association, with special attention to the timely administration of DTP (diphtheria, tetanus and pertussis).

The Commissioners also agreed that the societal benefits accruing from widespread availability of vaccines and full participation by families in pediatric immunization programs warranted a reassessment of the issues surrounding compensation for vaccine-related injuries. In summary, the Commission defined as its goals the following objectives:

- assurance of the continued development and availability of pediatric vaccines;
- assurance of continued participation of physicians and other qualified persons in administration of pediatric vaccines;
- assurance of appropriate vaccination of all children; and
- promotion of the identification and equitable compensation of persons injured by severe reactions to pediatric vaccines.

The Commission believes that these objectives will be promoted with adoption of the recommendations in this report.

Scientific Background

The Commission agreed that the following table fairly represents the most serious vaccine-related injuries that may arise in vaccinated children or adults contracting the disease by contact with these children:

VACCINE RELATED INJURIES IN THE UNITED STATES

Permanent Damage	*Estimated Incidence*	*Estimated Annual Doses*	*Estimated Annual Cases*
Brain damage from the P in DTP	3.2 per million*	13.5 million	43.2
Brain damage from the measles vaccine of MMR	1 per million	9.0 million (includes women of childbearing age)**	10*** 4 (future)**
Paralytic polio from TOPV	1 per 3.2 million	18.0 million	5 (known)**** nearly all in unprotected adults exposed to children given TOPV
Anaphylaxis (acute medical care only) from any vaccine	1 per 10 million (all vaccines)	50-60 million (all age groups)	5-6 (all age groups)

OTA Report
*British Medical Journal 282:1563, 1981
**Current "Catch-up" rate; projected to reduce to an annual rate of 4 million
***Modern Medicine 50:122-142, January 1982
****1980 Annual Summary MMWR 29 No. 54, September 1981

The recommendations contained in this report represent the views of the Commission. The participating organizations will each make their own determinations with respect to official endorsement of the Commission's recommendations.

In the Commission's deliberations it was readily apparent that brain damage and related severe neuropathy arising from adverse reactions to pertussis vaccine are now the most pressing concern. Therefore, deliberation on various compensation alternatives revolved around an analytical model based on the recent pertussis vaccine experience, with projections into the future years being made thereon. The Commission did note that clinical investigations of an alternative pertussis vaccine are in progress, but felt the exercise would be more valid if it reflected the nature, number and extent of injuries reported with the current vaccine. A brief discussion about the pertussis disease and vaccine injury was presented to the Commission and this is included in Appendix A.

Public Policy Considerations

The Commission received information from legal counsel regarding the historical development of pharmaceutical products liability standards in both common and statutory law. In assessing the adequacy of existing legal remedies and describing possible new ones, legislative and court imposed modifications (fault and no-fault) were evaluated.

Common Law

Pharmaceuticals, including vaccines, are "inherently dangerous products" in the lexicon of modern theories of tort liability. Such products are evaluated under a "negligence standard" when product related injury arises. If no negligence in product design, or production, handling, labeling and administration is discovered, a plaintiff in civil litigation may not prevail.

Our society has maintained this standard for vaccines because of the tremendous benefit flowing to a society free of those diseases for which vaccines are available. Maintenance of this standard recognizes that (1) vaccines cannot be made absolutely safe for all persons, and (2) some persons who are, in fact, injured by a vaccine with no attributable negligence may not have a civil remedy.

A description of the principles and legal standards applicable to vaccine liability cases is set out in the "Restatement, Torts 2d" (1965) section 402A, comments j and k; comment k provides:

> Unavoidably Unsafe Products.
>
> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degrees of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.
>
> ... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Current Legal Environment

Commission representatives noted the following problems attendant on civil litigation, above and beyond the concern the non-negligently injured persons might go without remedies: (1) new theories of liability (e.g., failure to provide adequate information to obtain a valid informed consent) are providing new avenues of recovery, thereby destabilizing the litigation (and risk management) environment; (2) there is widespread unhappiness over the extent of fees going to legal counsel, both plaintiffs and defendants, with the perception that the funds might be better directed to properly compensating claimants; (3) log jams in the courts and delay in legal process, and damages awarded out of proportion to injury, are destabilizing the tort litigation system and detracting generally from its public credibility and acceptance.

Legislative Options

The Commission considered legislative programs of vaccine compensation that could be pursued: federal law (fault or no-fault), state law (fault or no-fault), and federal law that places affirmative duties on the states (fault or no-fault). In addition, the Commission considered the issues of whether the proposed remedy would be optional, added to the tort remedies now available through the courts, or exclusive, whereby a legislatively imposed administrative remedy would preclude the customary civil litigation. Finally the Commission focused on the possibility of moving pediatric vaccine injury cases entirely out of the tort system by statute and moving them into a comprehensive statutory program.

Recommendations

By consensus, the Commissioners agreed that a federal legislative program should be pursued for the appropriate compensation of persons injured as a result of state mandated pediatric immunizations. After extensive debate, the following key elements were agreed upon:

1. **Exclusive vs. Optional Remedy.** There is unanimous agreement that an effective way to assure continued innovation and supply of vaccines, their proper and timely administration and to promote public participation is to remove the vaccine injury cases from the existing tort system. The proposed compensation system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available. The Commission recommends that the federal government become the substituted defendant for the vaccine producers and providers in all claims alleging vaccine-related injury from pediatric immunizations (DTP, measles, mumps, polio).

2. **Fault vs. No-Fault.** The Commission recommends that the legislation provide a no-fault entry to the claims review process. Should negligence on the part of the vaccine producer or provider be discovered in the course of administrative or legal review, the legislation should provide that the federal government can recover any award granted under the program from the negligent party.
3. **Scope of Coverage.** The Commission recommends that all persons seriously injured as a result of required pediatric immunizations be compensated. The proposed legislation would cover only those pediatric immunizations required by state law.
4. **Compensable Events.** The Commission recommends that the legislation direct the Secretary of the Department of Health and Human Services to constitute an expert advisory group to define those injuries and adversities that would be presumptively compensable under this program. The Commission recommends that the compensable events not be defined in the legislation, but be defined wholly by expert advisors and be subjected to notice and comment through "Federal Register" publication before final adoption.
5. **Extent of Compensation.** The Commission recommends that awards include the medical and other needed care, rehabilitation, special education and other strictly "compensatory" elements not covered under other programs. While most Commissioners are opposed to inclusion of "pain and suffering" awards, some agree that this may be a necessary element to enhance the political viability of the legislation. All agree that any "pain and suffering" compensation should be strictly limited and the award should run only to the injured party.
6. **Amount of Compensation.** The Commission recommends that the specific dollar amounts to be awarded by the Secretary be based upon a formula or formulas developed by an advisory committee to the Secretary comprised of experts with experience in this type of economic analysis. As with the advisory recommendations on the definition of compensable events, the Commission recommends that these formulas be published for review and comment before final adoption.

   There was strong sentiment in favor of the following elements being included in the legislative language that addresses development of formulas for damage awards:

   (1) structured settlements;
   (2) a clear statement of the limits of fees going to legal counsel;
   (3) a preference for regional formulas that give due credence to appropriate socioeconomic differences among regions, and;
   (4) administrative information gathering that focuses on local agencies as the locus for making judgments within the formulas as to the needs in individual cases.
7. Nature of Judicial Review. The Commission recommends that the legislation provide that the Secretary's determination as to eligibility for compensation and the amount of damages shall enjoy a presumption that "substantial evidence" supports the final judgment. Therefore, judicial review should be appellate in nature and not involve retrial of the facts.

Funding

A variety of proposals have been made as to the manner for funding federal legislation to provide new avenues of compensation to persons injured by participation in the national immunization programs.* The Commission does not have at its disposal the extensive information and resources necessary to adequately evaluate alternatives. It notes that a proposal to place a surcharge on each dose of vaccine administered in this country may not be the wisest, given the Commission's goal of full participation in pediatric immunization programs. The most desirable alternative might draw on trust funds coming from general revenues, thereby giving credence to the societal interest in and benefits from immunization programs without in any way burdening the programs or beneficiaries themselves.

Conclusion

The Commission finds that the medical community believes it can, in fact, identify those persons who have had severe reactions to the state mandated pediatric vaccines. With less than severe, irreversible injuries, the causal connection that medicine can state may be less precise. The Commission also finds great dissatisfaction with existing legal remedies as they pertain to injuries arising from mandated vaccines.

Of all of the armaments of medicine, vaccines offer the greatest potential benefit to the greatest number of persons. They also, however, continue to have statistically predictable incidence of very serious injury for a very few persons. The vaccine injury compensation program proposed here is intended to provide assurances to parents and their children, producers and providers of vaccines, that those who benefit so greatly from the prevention of disease and disability will care for those to whom state mandated immunization introduces disease and disability. This proposal equitably shifts existing burdens in such a way that society can:

—be assured of continued development and availability of pediatric vaccines;
—be assured of continued participation by physicians and other qualified persons in the administration of pediatric vaccines;
—be assured of the continuing appropriate vaccination of all children; and
—promote the identification and compensation of persons injured by severe reactions to pediatric vaccines.

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*Reports and Recommendations of the National Immunization Work Groups, submitted to the Office of the Assistant Secretary for Health, March 15, 1977.S. 2117 (98th Congress, 1st Session), "National Childhood Vaccine-Injury Compensation Act"; Congressional Record, Volume 129, pages S16612-S16621, November 17, 1983.

Members of the Ad Hoc Commission on Vaccine Injury Compensation:

Alan R. Nelson, M.D., *Commission Chairman*
AMA Board of Trustees
P. John Seward, M.D.
AMA Council on Legislation
Robert D. Burnett, M.D.
AMA Council on Medical Service
Joseph H. Skom, M.D.
AMA Council on Scientific Affairs
Harmon Holverson, M.D.
American Academy of Family Physicians
Martin H. Smith, M.D.
American Academy of Pediatrics
Jonathan B. Weisbuch, M.D.
American Association of Public Health Physicians
Glenn Molyneaux, M.D.
American Society of Internal Medicine
Donald N. Medearis, Jr., M.D.
Institute of Medicine
Marilyn Goldwater
National Conference of State Legislatures
Lynn A. Green, M.D., M.P.H.
National Medical Association
Barbara Walker, J.D.
Pharmaceutical Manufacturers Association
William Foege, M.D.
U.S. Department of Health and Human Services
Centers for Disease Control

APPENDIX A
Pertussis

Pertussis—The Disease

Pertussis (whooping cough) is an acute bacterial infection of the respiratory tract occurring primarily in young children. The exposed non-immunized neonate and young infant are nearly always susceptible, the attack rate approaching 100 percent.

Despite prompt intervention with antibiotics, neither the course nor morbidity of the disease is altered. (The prime value of antibiotic treatment is to reduce infectibility of the affected individual.) The most frequent, serious complication of pertussis is pneumonia. This complication is responsible for more than 90 percent of deaths in pertussis victims under three years of age. Neurologic complications include convulsions and coma, sometimes with residual brain damage, due to anoxia. Rare neurologic complications may include subarachnoid or intraventricular hemorrhage, meningoencephalitis, and an unexplained degeneration of the brain cortex. Specific complications are non-reportable, so their incidence is based on small samples. The Office of Technology Assessment of the United States Congress predicts a pertussis disease-related risk of encephalopathy as 8-140 per 1,000 (Compensation for Vaccine-Related Injuries, November 1980). A short review of this subject is given by Prensky (Developmental Medicine and Child Neurology 16:539-543, 1974).

The mortality rate with today's care has been reduced to about 5 per 1,000 cases of pertussis. (In 1926-1930, the fatality rate was 39.1 per 1,000.) The reduction in mortality may be attributed to various factors, including more effective management of secondary infections and greater accessibility to acute medical care. As recently as 1948, pertussis was a leading cause of death in children under 14 years of age. The mortality in the most susceptible group, infants, remains very high; 72 percent of pertussis deaths occur in children under one year of age.

Pertussis—The Vaccine

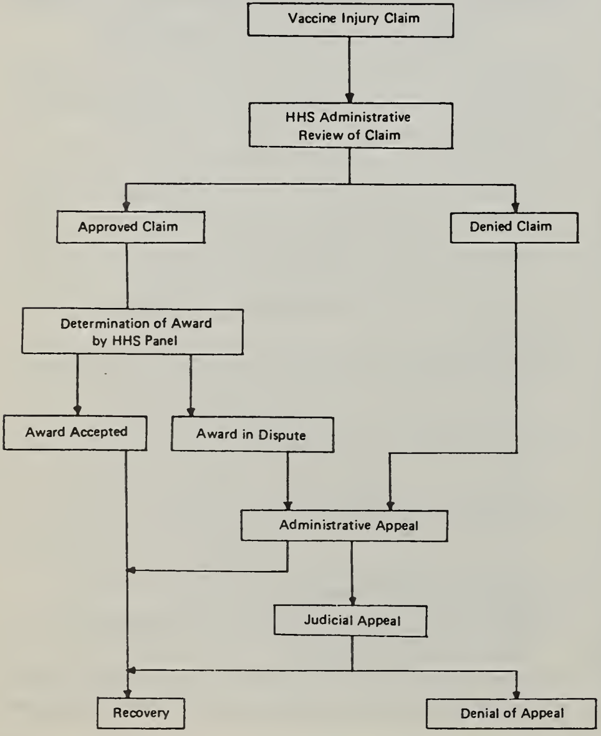
Immunization against pertussis uses a concentrated suspension of killed whole "Bordetella pertussis" organisms in a vehicle combined with diphtheria and tetanus toxoids (DTP). Moderately severe reactions to the vaccine occur which may be attributed to the pertussis component. These include convulsions and hypotonic hyporesponsive episodes, each of which occurs with a frequency of 1 per 1,750 vaccinations (Pediatrics 68:650, 1981). Acute encephalopathy following pertussis vaccination occurs with an estimated frequency of 1 per 110,000 vaccinations and residual damage is present one year later in approximately one-third of these individuals (British Medical Journal 282:1595, 1981). It is estimated that approximately 50 cases of permanent brain damage might occur each year in the United States if the risk of encephalopathy is the same for each of the five doses in a DTP series.

APPENDIX B
Elements of Vaccine Compensation Program Endorsed by the Commission

1. There would be established within the U.S. Department of Health and Human Services (HHS) an expert vaccine compensation advisory panel.
2. HHS, after mandated consultation with the expert panel, would be required to establish administratively a list of compensable vaccine injuries and clinical criteria for their documentation as vaccine-associated.
3. Eligible parties (as defined in the statute) would file a claim with the Department of Health and Human Services.
4. The Department of Health and Human Services professional staff would review claims pursuant to standards established and determine whether the claimant was injured, whether the injury or disability is within the class of designated compensable injuries, and whether it is vaccine-associated. HHS would have the power of subpoena, examination of the claimant, etc., at its discretion. Claimant would have the right to usual administrative appeal from denial of a claim.
5. Recovery would be limited to economic losses including medical expenses, costs of medical and vocational rehabilitation, wage loss, and any other out-of-pocket losses not compensated by other programs.

6. Once HHS staff had determined that a claimant had a compensable injury, the amount of the award would be determined pursuant to a compensation plan established administratively by HHS on advice of an expert advisory panel. Amounts in dispute would be dealt with within the appeal process.
7. Structured settlements (i.e., payments to be paid over time on a schedule) would be utilized in cases of injury/disability expected to last more than two years.
8. The vaccine compensation program would be an exclusive remedy: all claims for vaccine-associated injury or disability would be made only under the program.
9. When filing a claim for compensation by the government, there would be no need for the claimant to allege or prove fault. Furthermore, the claimant would not be permitted to pursue a tort action.
10. The federal government would have the right to bring an action against a program participant (i.e., vaccine manufacturer or health professional administering the vaccine) to recover amounts paid to claimants and associated expenses resulting from negligent acts or omissions.
11. Except for being subject to suit by the government (Number 10 above), all individuals involved in the manufacture, distribution, and administration of government designated vaccines would be immune from any legal action by vaccinees or their representatives for injuries and disabilities covered by the HHS program.

VACCINE COMPENSATION SYSTEM
PROCEDURE FLOW CHART



12. If a claimant's claim is denied, or the amount awarded is disputed, the claimant may appeal the decision to a federal court after exhausting administrative remedies. The Secretary would enjoy a presumption that substantial evidence supported her decisions; review would not be "de novo" but limited to a review as to whether the Department of Health and Human Services had properly interpreted and fulfilled its statutory obligations.

House Action: Adopted as Follows:

The Board of Trustees has reviewed the final Report of the Ad Hoc Commission on Vaccine Injury Compensation and is submitting it to the House of Delegates for its consideration. The formation of this Ad Hoc Commission and its recommendations are a direct response to Board of Trustees Report OO, "National Vaccine Injury Compensation Program (Substitute Resolution 9, 1-82)."

Although the recommendations contained in this report represent the views of the Ad Hoc Commission members, each participating organization will make its own determination with respect to official endorsement of this report.

The Board of Trustees recommends adoption of this report with the understanding that the AMA will, in implementation of the program proposed in the Commission's Report, also seek coverage of federally mandated pediatric immunizations.

Thomas Dover—Physician, Pirate and Powder, As Seen Through the Looking Glass of 20th-Century Physicians

MARTIN DUKE, M.D.

Dr. Thomas Dover (1662-1742) is remembered (a) for the eponymous attachment of his name to a well known mixture of opium and ipecacuanha called Dover's powder, a compound still mentioned in recent pharmacology texts, (b) for his discovery of a marooned sailor named Alexander Selkirk, an incident that is said to have provided the inspiration for Daniel Defoe's classic adventure story of *Robinson Crusoe,* and (c) for "The Ancient Physician's Legacy To His Country," a book that aroused considerable acrimony within the medical society when it was first published in 1732. In spite of the limited significance of these contributions to the history of medicine, Dr. Dover has continued to be a source of fascination to physicians for over two hundred years. The purpose of this paper will be to examine the diversity and at times conflicting images in which he has been portrayed, and to speculate whether writing about Dr. Dover with such frequency has served physicians as an outlet through which they have been able to express some of their own attitudes, hopes and desires.

Thomas Dover was born in Barton-on-the Heath, Warwickshire, England, matriculated from Magdalen Hall, Oxford, in 1680, and six years later entered Caius College, Cambridge, where he received his MB degree. He was a student of the famous Thomas Sydenham and later practiced medicine in Bristol, serving as a physician to the poor of St. Peter's Hospital. Between 1701-1707, Dover participated in several voyages involved in the prosperous slave trade between West Africa and the Caribbean. In 1708, he helped finance an around-the-work expedition to the South Seas. Although a mercantile venture,[1] the ships were also commissioned "to cruise on the coasts of Peru, and Mexico, in the South Seas against her Majesty's enemies the French and Spaniards." Dover was third in command, a position probably given to him on the basis of his financial involvement. It was during this voyage that Alexander Selkirk ("Robinson Crusoe") was found by Dr. Dover on the Island of Juan Fernandez off the coast of Chile. Later, Dover participated in plundering the two cities of Guaiaquil, as a result of which he acquired a reputation as a pirate, buccaneer, or privateer, depending upon one's point of view and the subtle distinctions between these occupations. Financially, this was considered one of the most successful pirate expeditions of British maritime history. In the years that followed, Dover was deeply involved with the famous (infamous ?) South Sea Company, working for British commercial interest in South America and serving as the first president of the company's trading post in Buenos Aires. However, Dover's irregular and unorthodox form of management and "Breach of his Instructions and neglect of Duty" led to his eventual dismissal from this position.[2]

Returning to England in 1717, Dover secured a license to practice medicine in London. Here, he wrote the previously mentioned book entitled "The Ancient Physician's Legacy to His Country." The title page (Figure 1) indicated that it was meant for the laity rather than for fellow physicians—"An account of the several diseases incident to mankind, described in so plain a manner that any person may know the nature of his own disease. Together with the several remedies for each distemper, faithfully set down. Designed for the use of all private families." It would appear that "how to" books and advertising techniques of this type are not only a phenomenon of recent years. In addition, Dover was not one to shrink from expressing strong opinions, as seen from his many disagreements during the South Seas Voyage, and his polemics against the high fees and unethical practices of apothecaries and fellow physicians. Because of his liberal use of mercury for treating a variety of ailments, he was called the "Quicksilver Doctor," although it is rather through the enduring Dover's powder that his medical notoriety still reaches us after nearly 250 years. Continuing medical practice

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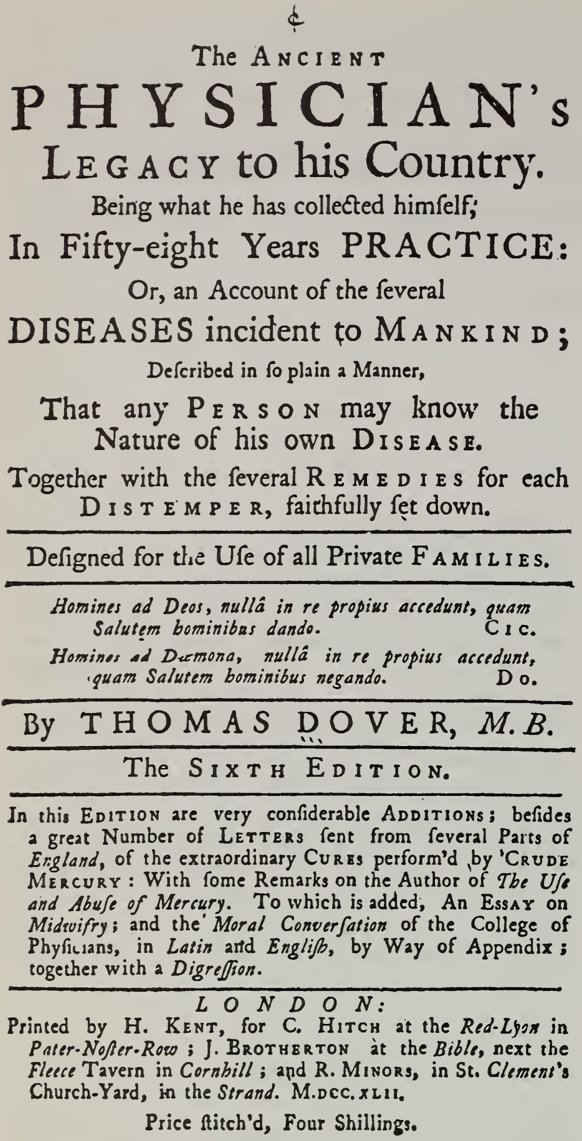
MARTIN DUKE, M.D., Cardiologist, Manchester Memorial Hospital, Manchester, CT; Assistant Clinical Professor, Department of Medicine, University of Connecticut School of Medicine, Farmington, CT.



The Ancient
PHYSICIAN's
Legacy to his Country.
Being what he has collected himſelf;
In Fifty-eight Years PRACTICE:
Or, an Account of the ſeveral
DISEASES incident to Mankind;
Deſcribed in ſo plain a Manner,
That any Person may know the
Nature of his own Disease.
Together with the ſeveral Remedies for each
Distemper, faithfully ſet down.

Deſigned for the Uſe of all Private Families.

Homines ad Deos, nullâ in re propius accedunt, quam Salutem hominibus dando. Cic.
Homines ad Dæmona, nullâ in re propius accedunt, quam Salutem hominibus negando. Do.

By THOMAS DOVER, *M.B.*

The Sixth Edition.

In this Edition are very conſiderable Additions; beſides a great Number of Letters ſent from ſeveral Parts of *England*, of the extraordinary Cures perform'd by Crude Mercury: With ſome Remarks on the Author of *The Uſe and Abuſe of Mercury.* To which is added, An Essay on *Midwifry*; and the *Moral Converſation* of the College of Phyſicians, in *Latin* and *Engliſh*, by Way of Appendix; together with a *Digreſſion.*

LONDON:
Printed by H. Kent, for C. Hitch at the *Red-Lyon* in *Pater-Noſter-Row*; J. Brotherton at the *Bible*, next the *Fleece* Tavern in *Cornhill*; and R. Minors, in St. *Clement's* Church-Yard, in the *Strand*. M.DCC.XLII.

Price ſtitch'd, Four Shillings.

Figure 1.
Title page for the sixth edition "The Ancient Physician's Legacy To His Country"

until the age of 80, Dover retired to his native Cotswolds where he died shortly thereafter.

In 1896, Sir William Osler[3] wrote "Thus it happens that Thomas Dover, the Doctor, has drifted into our modern life on a powder label . . . while Thomas Dover, the Buccaneer . . . has been forgotten." In regard to the South Seas expedition, he described how "the expedition sacked the two cities of Guaiaquil, in the assault of which Dover led the van. To Dover . . . fell a considerable share of the spoils." To assist his practice and advertise his use of quicksilver, Dover "resorted to the time-honored plan of writing a book." Indeed, "if Dover's object in writing a book was to gain publicity, he could not have taken a better way than in his sharp comments on the physicians and apothecaries." To further fan the flames of controversy (and interest), Osler quoted Dr. Daniel Turner, a contemporary of Dovers: "I think the Doctor (Dover) had much better have left out his Bravado of having taken two cities by storm, unless he thinks it an honour to a Physician to kill and slay, and after to plunder the Innocent, those who never wronged him, and to carry off the spoil." Osler added—"Doubtless the old buccaneer, described as a man of rough temper, who could not easily agree with those around him, was a striking figure as he passed along the Strand to the Jerusalem Coffee House, where he saw his patients." In essence, Osler describêd a rascal with whom one might not want to associate, but about whom one might vicariously enjoy reading.

Following Osler's detailed article about Dover, others soon appeared. Some emphasized the unsavory but intriguing aspects of Dover's activities, while others tried to present him in a more favorable light. An article in the Medical Press[4] in 1902 stated "Old Dover was no savant. He discovered no bacillus; he was a good way on the road to quackery, and yet I fancy his life is better worth narrating than are those of half of the famous men of medicine stamped with the hall-mark of any university whatsoever." Nixon[5] admitted that Dover was an "extremely cantankerous travelling companion" and a "hot-tempered navigator," but he attempted to soften and minimize the pirate image by titling his article "Thomas Dover; Physician and Merchant Adventurer." He added that the expedition "was in no sense of a piratical nature . . . his (Dover's) buccaneering amounts to accompanying in person one of the numerous trading expeditions which set out from Bristol and other ports to obtain by purchase or persuasion the produce of the New World, and, if Fortune smiled, the rich cargoes of sundry foreign galleons."

As mentioned by Downie,[6] "buccaneering was considered to be a legitimate occupation. It appealed to the sporting instincts, as it bore promise of adventure and excitement with high stakes." He hastened to add, however, that "one can scarcely conceive of a doctor . . . taking a leading part in the operation of such an expedition." Downie also commented that Dover's book was meant for self aggrandizement and personal gain—"he was not over scrupulous in many of his actions"—further adding that "I have given you in this address some details of the varied life of Dr. Thomas Dover, but they were not given to you with the intention of holding him up as a pattern for your imitation."

Dover was described by Skirving[7] as a "bluff, hearty, headstrong Englishman with some likeable qualities. If he had lived in 1914, he would, I don't doubt, having joined up—probably as a combatant of some sort—where he would at least have shown courage if not wisdom . . . . No, let us not forget this quaint and masterful member of our profession."

"Pirate and Buccaneer Doctor"—not much question that Leo Eloesser was attempting to excite the imagination of his readers[8]—"Dr. Dover, sea rover, and originator of the pulv. ipecac. et opii comp. A squabbling, irascible, Paracelsian character, with considerable of the mountebank even for those eighteenth century days; author of a medical manual for laymen; always quick to pick a quarrel with his colleagues; an opinionated stubborn man." After a brief review of Dr. Dover's medical life and contributions, Eloesser appeared happy to change the subject—"Let us leave Dr. Dover. Captain Dover is more entertaining." Recounting his buccaneering exploits, Eloesser concluded—"Your memory therefore is assured, Captain Dover, even though your powder and quicksilver, Dr. Dover, he forgotten. Robinson Crusoe, Defoe and Captain Woodes-Rogers have saved you."

A similar profile of Dover was presented by Boyes[9] who asked the question "How, then, shall we remember Dover? As a buccaneer, his ability was undoubtedly greater than as a physician, yet in the latter role he devised a powder which has survived two centuries. Might we not, however, better recall him as the rescuer of Robinson Crusoe, the means of bringing us one of the favored stories of each succeeding generation? A man who had the love of adventure so ingrained in him that, at an age when most of us are looking forward to a few years of peace and comfort, he organized an expedition, accompanied it, and led it in battles .... Such a man would, I am sure, much rather be remembered as Captain Dover, Buccaneer, than as Dr. Dover, Bachelor of Medicine." (Could it be that the MB degree stood for Master of Buccaneering?)

A novel and interesting thought about Dover was expressed by Howell[10]—"Few modern medical books are likely to give pleasure to their readers two hundred years hence. The twentieth century author, acutely conscious of the rapid advance of knowledge and feeling that his views may soon be superseded, adopts an impersonal tone which sounds dry and insipid after a few decades. What a contrast this is to such a book as "The Ancient Physician's Legacy To His Country" by Thomas Dover! Of course, a great deal of the charm of this little volume is due to the character of the writer, but how pleasant it is to grasp the author's personality, instead of merely having to be content with his name, qualifications, and appointments .... After 210 years Dover's *Legacy* is still fascinating, vivid. Its swashbuckling, truculent author lives for ever in the pages of his book as well in the formula of his powder. Will the same be said for any medical author writing today, I wonder?" With descriptions like these, one has little difficulty in imagining the film version of Doctor Dover portrayed by the likes of movie heroes such as Douglas Fairbanks, Errol Flynn or Tyrone Power.

More recently, Monk,[11] in an added fillip to the saga of Dover's powder, wrote "Dover made one ingenious therapeutic innovation that has perhaps been undeservedly neglected. He prescribed opiates widely for their analgesic properties but combined them with a small amount of ipecacuanha, so that, if taken in an excessive dose, they would be vomited back ... perhaps when so many of our emergency hospital admissions are due to drug overdoses, Dover's concept of an analgesic—emetic combination will prove too valuable to be consigned to the history books."

In reviewing Dr. Dover's life and his accomplishments, especially as romanticized by those who wrote about him, perhaps a bit of what we all would like to be but dare not is appealed to. Call Dr. Dover pirate, buccaneer, sea captain, rogue, navigator or adventurer, a man against the machine, an anti-establishment individualist—is there not some of this in all of us? Do we not all secretly want at some time to escape to a South Seas Isle? Do we not all want at some time to tilt against windmills in our present society, be it the government, unions, big business, or medical societies? Would we not all be interested in a bit of privateering, opportunity presenting itself? Is not the image of Treasure Island and Long John Silver conjured up in this man? Would not our vanities be touched if we knew we had a medicine or discovery named after us that future generations might remember and even be using 250 years later? Do not many of us harbor secret ambitions to be an author of a book?

There are physicians unknown to us who have made greater contributions to mankind and are more deserving of fame than Dr. Dover. He, however, is remembered and even admired by us, not necessarily because of his contributions but because of his uniqueness and "joie de vivre" that many may secrectly envy, but except in their imaginations, dare not emulate. He appeals to our spirit of adventure, a spirit that within the rigorous confines of medical practice is often unable to find an outlet. Through Dr. Dover, we can, like Walter Mitty,[12] seek this outlet, and by so doing, momentarily escape from the realities around us. This, I believe, might explain why interest has been shown by so many writers in such a minor personage, and why we all enjoy reading and writing about him. Although piracy by physicians is hopefully no longer in vogue, such ventures as the Peace Corps, Project HOPE, and other similar experiences can still provide opportunities for the imaginative and adventuresome, and perhaps serve to channel the spirit of Dr. Dover into the present.

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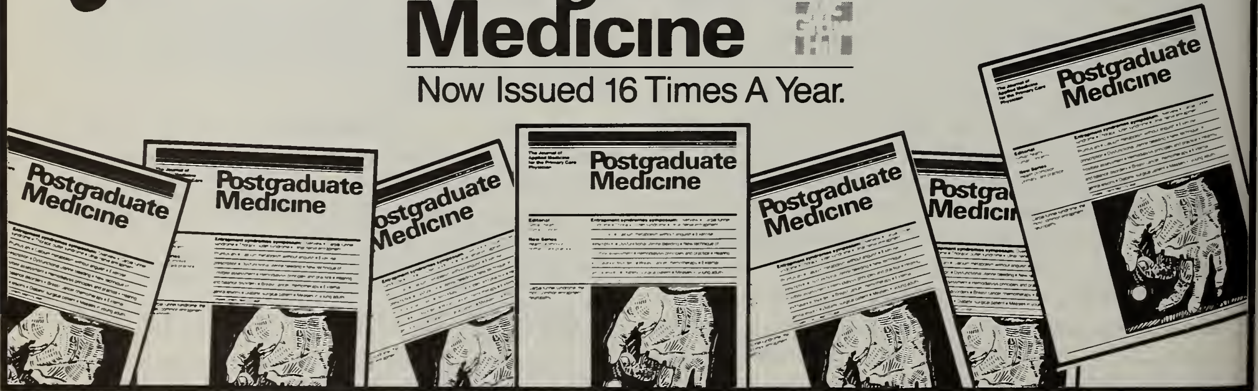

Month in Washington

Medicare/Medicaid Cuts Foreseen In Budget

As the Reagan Administration continues to develop and revise its 1986 budget proposal, Congressional reaction seems to indicate that lawmakers may tinker with the proposed Medicare and Medicaid cuts. If the cuts become part of a general freeze on all federal programs, however, modifications are much less likely. Among the areas where Congress would change the President's proposal are Medicare freezes on payment levels to physicians and hospitals, reductions in federal Medicaid funds, and increases in cost-sharing for Medicare beneficiaries.

Although the President has acknowledged that his budget proposal will include a one year extension of the current freeze on physician fee levels, details of the plan have not been made available. There are strong signals that the proposal will apply to all physicians, including those who signed "participating physician" agreements last fall.

One incentive for signing the participating agreement—which commits the MD to accepting the Medicare fee level as full payment for all cases—was the promise of a potentially higher fee allowance at the conclusion of the current freeze on October 1, 1985.

Congressional staffers report that some lawmakers are therefore reluctant to freeze fees of participating physicians because they see this as reneging on a financial commitment they made to these MDs. Other members are said to believe freezing fees of the participating physician would in effect terminate an experiment they want to continue.

The President also has announced that he wants to freeze Medicare payment rates for hospitals. Under current law, hospital rates would be permitted to increase by a percentage equal to the increase in the market basket of goods and services they purchase plus 0.25%. Under the budget proposal, no increase would be permitted.

Hospitals are concerned that the proposed freeze could mean that some institutions, rather than receiving the same payment per case in 1986 as in 1985, would actually receive lower payments.

Industry officials who argue that many of these may be institutions that have higher costs because they provide more indigent care, treat sicker patients or are located in high cost areas are calling for protection for some of these facilities.

Several alternatives have emerged. One would simply provide that no hospital would receive a lower payment per case in 1986 than in 1985, this "holding (the hospitals) harmless." Another would freeze the current 50-50 split between the hospital specific and the national portions of the DRG rate. A third proposal, backed by the American Hospital Association, would blend the national and hospital specific rate separately for each DRG based on how much costs for the particular DRG varied among hospitals.

Hospital spokesmen say they believe there is support for both a "hold harmless" proposal and a phase-in freeze. In addition, a preliminary study from the Congressional Budget Office, while not endorsing the AHA-proposed blending approach, has concluded that blending would be accomplished without any increase in DRG rates and that it would narrow the range of gains and losses that hospitals would experience under a fully-national DRG rate.

Lawmakers are also worried about cuts that could harm beneficiaries. Health and Human Services Secretary Margaret Heckler has suggested that an Office of Management and Budget proposal to raise the Medicare Part B premium to cover 35% of program costs by 1990 be modified to cover only 30% of costs. Two influential Senate Republicans, Majority Leader Robert Dole of Kansas and Senate Finance health subcommittee chairman David Durenberger, reportedly are ready to offer the Heckler proposal as an alternative. Democrats can be expected to press for the reduction or elimination of increased beneficiary cost-sharing.

Even more controversy has arisen over the President's call for a $1 billion reduction in federal Medicaid expenditures in fiscal 1986 and a cap that in following years would permit increases only equal to the rise in the gross national product deflator. The administration is now said to have modified the plan by creating a $300 million fund to help states that were unable to curb Medicaid costs despite "good faith efforts."

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Medicare Offers HMO Option

A new prospective payment option for Medicare HMO enrollees, scheduled to take effect February 1, is expected

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Prepared by the Washington, D.C.
Office of the American Medical Association

to encourage up to 800,000 Medicare beneficiaries to join HMOs or other competitive medical plans within the next three or four years.

Final regulations to implement the new payment method were published in the Federal Register on January 10. The reimbursement change, which results from a 1982 law, would institute a program that American Medical Association delegates have urged be delayed.

Substantial changes have been made in the rules since they were first proposed last May. The most significant is a requirement that Peer Review Organizations review the care of Medicare HMO enrollees.

The new rules give HMOs, preferred provider organizations and other alternative delivery plans two payment options. The plan may either continue under the cost-based arrangements nearly all HMOs operate under today. Or it may be paid a prospective monthly fee for each of its Medicare beneficiaries.

Under the prospective payment, HMOs would receive up to 95% of Medicare's average cost per beneficiary in the community for each Medicare HMO enrollee. Adjustments would be made for age, sex and institutional status of the Medicare enrollees.

The HMOs or other prospectively-paid plans must provide benefits at least equal to those of Medicare. If the plan's cost of providing care to Medicare recipients is less than 95% of Medicare's so-called average adjusted per capita cost, the HMO must accept a lower payment or provide more benefits to Medicare enrollees. Plans may charge a premium to cover the costs of extra services and premiums are expected to range from $20 to $50.

Beneficiaries would still be liable for the monthly Part B premium and could also still be held responsible for cost-sharing equal to the current liability in the standard Medicare plan. Based on the experience of HMOs participating in a demonstration of a similar Medicare financing arrangement, many of the plans are expected to reduce or eliminate current cost-sharing, however.

Twenty-one HMOs have participated in the demonstration but an evaluation of the demonstration has not been completed. The demonstration did show that large numbers of Medicare beneficiaries will enroll in HMOs when offered new benefits not covered by Medicare.

It has also raised some concerns, however, particularly in Florida, where the General Accounting Office is investigating one demonstration plan—the International Medical Centers. Other concerns about the new payment method have centered primarily on costs, potential withholding of needed services, and administrative feasibility of calculating the average adjusted per capita cost.

* * * *

Medicare "Participation" at 30%; Accepted Claims Rise

About 30% of physicians treating Medicare patients signed "participating agreements" with the program in fiscal 1984. At the same time, the number of claims for which physicians accepted Medicare fee allowances as full payment rose to a record 66.5% in November of last year.

The physician sign-up rates varied by state and by specialty, ranging from 5.6% in South Dakota to 53.9% in Alabama and from 18.2% for some miscellaneous surgical specialties to 50.8% for nephrologists.

The "participating" concept was established in legislation enacted last fall and now under challenge in federal courts by the American Medical Association, the Indiana Medical Society and some individual physicians. The law froze Medicare fees for all physicians until October 1985 and provided financial and administrative incentives for practitioners who agreed to "participate." Participating physicians must accept assignment on all Medical claims, billing the patient only for the 20% of the Medicare allowable fee that is not paid by the program.

In fiscal 1984, about 56% of Medicare claims were taken on assignment and about 20% of physicians reportedly always assigned claims, according to HCFA. In fiscal 1985, some 118,428 physicians, or 29.8% of those treating Medicare patients, signed participating agreements. Assignment rates, which had been rising slowly since 1976, jumped to 66.5% of all claims, or 5% higher than their previous high of 61.5% in 1969, HCFA says.

In addition to physicians, some 19,751 or 34% of nonphysician practitioners treating Medicare patients and 17,822 or 23.8% of Medicare suppliers signed agreements.

In three states and the District of Columbia, more than half of all physicians with Medicare patients signed participating agreements, HCFA reported. Following Alabama were Kansas and the District at 52.9% and Pennsylvania at 51.1%. Other states where more than 40% of physicians agreed to participate are New Mexico (48.6%), Massachusetts (47.9%), Rhode Island (46%), Arkansas (44.6%), Michigan (43.4%) and Vermont (42.2%).

In South Dakota, only 5.6% of physicians agreed to participate and in Alaska 9.4% signed agreements. Other states with participating rates of less than 15% are North Dakota (10.4%), Idaho (11%), Oklahoma (12.8%), South Carolina (13.5%), and Oregon (13.8%).

Among physician specialty groups, the highest sign-up rates occurred among nephrologists, who typically treat large percentages of Medicare patients under the program's End Stage Renal Disease Treatment coverage.

The hospital-based specialties of radiology (41.3%) and pathology (39.6%) also showed higher than average sign-up rates while anesthesiologists were at 21.1%.

Peer Review Suit Filed By Hospital Association

Making good on a long-standing threat, the American Hospital Association has sued the federal government over its implementation of Medicare peer review organizations (PROs).

One issue in the suit—the issuance of four sets of final PRO regulations—may be close to resolution, however, with reports that the regulations have cleared a snag in the Office of Health and Human Services Secretary Margaret Heckler and been sent to the Office of Management and Budget.

The regulations govern the way PROs conduct review, the appeals and sanctions processes, and the confidentiality of PRO data. Both hospitals and PROs have complained about the lack of final regulations. Minnesota Republican Senator David Durenberger has said that one of his first items of business as chairman of the Senate health subcommittee will be hearings on the program.

PRO supporters hope the AHA legal action and the promised hearings will forestall implementation of the program.

Another snarl in the overall implementation of the program has arisen, however, with the decision by PRO officials to reopen bidding on a so-called Super PRO contract. Four bids reportedly were received on the contract but the only organization which has publically acknowledged its bid is the American Medical Association.

AHA's decision to sue the government came six months after the organization, representing 7000 hospitals, first charged that the numerical objectives in PRO contracts amounted to "quotas" to reduce Medicare hospital admissions by 1.25 million in two years.

An earlier threat to sue was dissipated by repeated assurances from HCFA officials that the contract objectives would be renegotiated if they proved unreasonable. In recent months, AHA officials had said they were "cautiously optimistic" that their problems with the PRO program could be worked out. Association spokesman said the decision to proceed with the suit resulted from "membership pressure." HHS Secretary Margaret Heckler cancelled a scheduled appearance at an annual AHA meeting after learning of the suit.

Filed January 29 in the U.S. District Court in the District of Columbia, the lawsuit does not seek to stop the operation of the PRO program. Instead it complains of inadequate public accountability in the installation of the program and calls on HHS to follow the Administrative Procedures Act in implementing the review system. HHS will have 60 days to answer the AHA complaint.

* * * *

Doctor Draft Revisited

The Pentagon should draft doctors and other health care professionals for rapid induction in the event of a war, according to a Heritage Foundation report released in January.

The U.S. Armed Services are short 60,000 medical specialists and could only treat a small fraction of the battlefield wounded if large-scale conventional warfare breaks out, said the author of the report, former director of the Army Reserve Maj. Gen. Henry Mohr (USA-Ret).

The report recommended immediate registration of all persons between the ages of 18 and 46 who are trained in health care occupations. Both women and men should be drafted, he said, as well as all persons with technical medical skills.

Yielding to heavy opposition from the American Medical Association, American Nurses Association, the American Public Health Association and other groups, the Pentagon recently abandoned a peacetime registration plan for drafting doctors and other healthcare workers.

A draft discriminates against physicians and other health care professionals because it would subject them to a special military registration and to potential induction throughout their lives, AMA said. Increased efforts to recruit physicians—by offering attractive benefits, for instance—would boost health health manpower, the AMA believes.

Under current Pentagon plans, a physician draft will be part of a broad "Mobilization Day" registration plan, to be handed over to Congress only in the event of "World War III or another national emergency," said a Pentagon spokesman.

* * * *

Oral Dosage Drug For Herpes Cleared

The Food and Drug Administration in January a pill to treat genital herpes.

The oral dosage form of acylovir will be marketed under the name Zovirax. It will join the intravenous and ointment forms of the drug in attempting to capture the $220 million herpes market. The product is manufactured by Burroughs Wellcome Co. and could aid the 5 million to 20 million Americans believed to be affected by the disease.

* * * *

New Cesearean Guidelines Issued

The American College of Obstetricians and Gynecologists (ACOG) has issued new guidelines that encourage women who have had a previous cesarean birth to deliver their next child vaginally.

As many as 280,000 of the 700,000 cesarean births performed each year are indicated because of a previous cesarean delivery. Of these women, roughly 100,000 could instead have a safe vaginal birth, ACOG said.

ACOG's new guidelines, could slow the steady rise in the number and rates of cesarean births. Of all cesarean births, 55% are due to a previous cesarean, 24% are due to "failure to progress" in labor, 13% are due to fetal distress, and 5% are due to breech presentation of the infant.

* * * *

Aspirin/Reyes Warning Set

Aspirin manufacturers this month agreed to develop new labels that warn of a possible link between aspirin and Reyes syndrome.

Their action was based on newly released data from a Centers for Disease Control study which reveals a strong association between the children's disease and the use of aspirin.

Researchers found that 97% of children with Reye's Syndrome were reported to have used aspirin during respiratory or chickenpox illnesses before the onset of Reye's Syndrome. Of control case groups without Reyes syndrome, between 28% and 55% had received aspirin for matching illnesses.

In response to HHS Secretary Margaret Heckler's request, aspirin manufacturers voluntarily agreed to:

- place a warning on aspirin packages.
- discontinue any promotion for use of their produce in cases of flu or chicken pox.
- warn that physicians be notified before use of aspirin in cases of flu or chicken pox.

The reduced incidence of the disease over the past several years—from 454 cases in 1975 to 190 cases in 1984—has been attributed to the decline in the use of aspirin among young children.

* * * *

Vaccine Woes Heard On Capitol Hill

Unless government stockpiles are substantially bolstered and manufacturers are relieved of some liability, other vaccines could suffer the same fate as the diptheria, tetanus, and pertussis (DTP) vaccine, Congress was warned this month.

Two lots of the DTP vaccine recently failed to meet potency standards, creating a sudden shortage of 2 million doses of the vaccine. The shortage forced physicians across the country to postpone booster shots to any child more than a year old.

Levels of oral polio vaccine (OPV) have also taken an unexpected dive. Last summer, when Lederle Labs removed aging doses of OPV from government stockpiles to distribute to physicians, backup supplies dropped from 3.4 million doses to 600,000 doses. If production had been suddenly interrupted, the nation would have had less than 12 days supply of the polio vaccine.

The situation has not created a health crisis at this time. Most children are already immunized against the diseases and partial immunizations are not expected to reduce immunity. But Congress and the medical community believe the government should protect itself from fires, explosions, potency problems, and other sudden interruptions in vaccine production.

"At best, we are in a situation with an uncertain vaccine supply. At worst, there could be dangerous shortages, postponements of immunizations, and outbreaks of disease," said Alan R. Nelson, MD, Board member of the AMA, at a January hearing before a House subcommittee.

The stockpiling program falls far short of national needs, charged Rep. Henry Waxman (D-CA) and other members of Congress. Because the Reagan Administration has failed to provide adequate funding, vaccine stockpile levels stay dangerously low, they said.

The problem could be eased by making the vaccine business more attractive to manufacturers by reducing the number of lawsuits, witnesses said. The present dollar demand of DTP lawsuits against Lederle is 200 times greater than their total sales of the vaccine in 1983.

Within the medical and congressional communities, there is general agreement that Congress should take steps to compensate children and families injured by vaccines. A federally sponsored compensation program, financed by a general revenue trust fund or a surcharge on each dose of vaccine, could also reduce the number of lawsuits, proponents believe.

* * * *

Anti-Abortion Bills Sent To Congress

The first of a series of anti-abortion bills was introduced in the Senate's opening days in January.

The bill, called the "Unborn Children's Civil Rights Act of 1985" (S. 46), was introduced by Sen. Jesse Helms (R-NC) and Gordon Humphrey (R-NH) and endorsed by a coalition of anti-abortion groups.

The proposed legislation states that:

- scientific evidence demonstrates that abortion takes the life of an unborn child who is a human being,
- the right to an abortion is not secured by the Constitution, and
- the Supreme Court, in its Roe v. Wade decision, erred in not recognizing the humanity of the unborn child.

It also denies federal funding for abortion and fetal research, except to save the lives of the mother or child.

* * * *

Organ Task Force Formed

The new Task Force on Organ Transplantation, established by the Department of Health and Human Services this month, will begin reviewing the nation's organ transplant network in February.

The task force, authorized by the National Organ Transplantation Act of 1984, will advise HHS on the medical, lethal, ethical, economic, and social aspects of organ transplantation. It also will advise HHS on the feasibility of setting up grant programs to develop new procurement organizations and networks.

It must report to HHS and Congress on issues of immunosuppressive drugs by July and prepare a final report by next January.

The Connecticut General Assembly 1985-1986

RAYMOND T. SULLIVAN, JR.

The legislature of the State of Connecticut is known as the General Assembly and consists of the Senate and the House of Representatives. In accordance with the Constitution adopted in 1965, legislators are elected to both houses for two-year terms from single-member districts of substantially equal population. The General Assembly meets at the State Capitol in Hartford.

SESSIONS

Regular Sessions

Odd-numbered years: Held beginning on Wednesday following the first Monday in January and adjourning not later than Wednesday following the first Monday in June.

Even-numbered years: Held beginning on the Wednesday following the first Monday in February and adjourning not later than Wednesday following the first Monday in May. The even-year session shall consider no business other than budgetary, revenue and financial matters, bills and resolutions raised by committees of the General Assembly, and those matters certified in writing by the Speaker of the House of Representatives and President Pro Tempore of the Senate to be of an emergency nature.

Special Sessions

These may be called by the Governor in emergencies and upon petition by a majority of the elected members of each house.

Post-Adjournment Session

Following a regular or special session in which any bills vetoed by the Governor have not been reconsidered, the Secretary of the State must reconvene the General Assembly for the sole purpose of acting on such bills.

MEMBERSHIP

The Senate

36 Senators, one from each of the 36 Senatorial Districts. (The Constitution provides for not less than 30 and not more than 50 members.) Current political party composition: 12 Democrats, 24 Republicans.

The House

151 Representatives, one from each of 151 Assembly Districts. (The Constitution provides for not less than 125 and not more than 225 members.) Current political party composition: 66 Democrats, 85 Republicans.

Term of Office for Senators and Representatives is two years; Elections are held in November of even-numbered years; Annual Salaries are $13,000 plus $2,500 for expenses, plus .20¢ per mile travel allowance.

MAJORITY AND MINORITY LEADERS

They preside over party caucuses, direct party strategy, assemble party members for important votes, serve as spokesmen for parties in dealing with the Governor and the press, serve as ex-officio members of all committees. In each house, the minority members of committees are appointed on nomination of minority leadership.

Senate Officers

President: Joseph J. Fauliso (D), by virtue of his office as Lieutenant Governor, presides over the Senate; refers bills to appropriate committees.

President Pro Tempore: Philip S. Robertson (R), elected by Senate; presides over the Senate in the absence of the President; appoints Senate chairmen and members of committees.

Majority Leader: Reginald J. Smith (R), elected by majority party members.

Deputy Majority Leaders: Thomas Scott (R), Anne P. Streeter (R) and John G. Mathews (R), elected by majority party members of the Senate.

Majority Whips: Michael L. Morano (R) and Thomas F. Upson (R), appointed by the Senate President Pro Tempore.

Assistant Majority Leaders: M. Adela Eads (R), Richard Johnston (R) and Richard S. Eaton (R), appointed by the Senate President Pro Tempore.

Minority Leader: Cornelius O'Leary (D), elected by Senate minority party members.

Deputy Minority Leader: Amelia P. Mustone (D), appointed by Senate minority leader.

Assistant Minority Leaders: Steven C. Casey (D), John C. Daniels (D), William A. DiBella (D), Joseph H. Harper, Jr. (D), Kevin P. Johnston (D), Margaret E. Morton (D) and Anthony D. Truglia (D), appointed by Senate minority leader.

RAYMOND T. SULLIVAN, JR., Assistant Executive Director Public Affairs and Legislation.

House Officers

Speaker of the House: R. E. Van Norstrand (R), elected by the House of Representatives; presides over the House; appoints House chairmen and members of committees; refers bills to appropriate committees.

Deputy Speaker: Richard O. Belden (R), appointed by the Speaker.

Majority Leader: Robert G. Jaekle (R), elected by the majority party members of the House.

Deputy Majority Leaders: Edward C. Krawiecki (R) and Julie D. Belaga (R), appointed by the Speaker of the House.

Majority Whips: John J. Zajac, Jr. (R) and Sidney J. Holbrook (R), appointed by the Speaker of the House.

Assistant Majority Leaders: Frank J. Esposito (R), Robert Farr (R), Richard Foley, Jr. (R), Carol A. Herskowitz (R), Sidney J. Holbrook (R), Paul Karbowski (R), Pauline R. Kezer (R), Martha D. Rothman (R) and John J. Zajac, Jr. (R), appointed by the Speaker of the House.

Minority Leader: Irving J. Stolberg (D), elected by the minority party members of the House.

Deputy Minority Leader: Robert F. Frankel (D), appointed by the Minority Leader.

Assistant Minority Leaders: Richard J. Balducci (D), Teresalee Bertinuson (D), William J. Cibes, Jr. (D), William R. Dyson (D), John Wayne Fox (D), Robert G. Gilligan (D), William Kiner (D), Dean P. Markham (D), Timothy J. Moynihan (D), Mary Mushinsky (D), Mark Healey Powers (D), John J. Woodcock III (D), appointed by the Minority Leader.

ORGANIZATION

At the beginning of each session, the Senate and House of Representatives adopt separate rules for the conduct of business in plenary session. They also adopt joint rules for joint committees and procedures. Joint conventions are held to inaugurate the Governor and other state officials, to receive the Governor's message, to receive the Governor's budget message in February and for business as may be required.

COMMITTEES

All committees of the General Assembly are joint committees composed of both senators and representatives. In the 1985-1986 term, there are twenty-one committees, eighteen of which are responsible for examining and screening bills and resolutions. Three committees (Staff Internships, Program Review and Investigations and Regulation Review) are composed of equal numbers of members from each political party and have special responsibilities. All committees function during interim as well as sessional periods. The committees are:

Appropriations;
Banks;
Education;
Energy & Public Utilities;
Environment;
Executive & Legislative Nominations;
Finance, Revenue & Bonding;
General Law;
Government Administration & Elections;
Human Services;
Insurance & Real Estate;
Judiciary;
Labor & Public Employees;
Legislative Management;
Planning & Development;
Program Review & Investigation;
Public Health;
Public Safety;
Regulation Review;
Staff Internships;
Transportation.

N.B. Literally thousands of bills have been put into the legislative hopper so far this session. Hundreds of them deal with medical and health matters. Many of these will have a profound effect on your patients, your practice and your income. CSMS members who wish to have a say in these matters are urged to contact Mr. Ray Sullivan at Society headquarters in New Haven.

Call 865-0587

Changing Medical Practice Arrangements

AMA CENTER FOR HEALTH POLICY RESEARCH

Over the past decade, there have been significant changes in the medical practice environment. An increasing supply of physicians, increasing cost-consciousness among medical consumers and third-party payors, advances in medical technology, rising costs of medical practice and increasing liablility risk have lead physicians to alter practice arrangements. This report examines trends and variations in:

- traditional practice characteristics, including the size of practices, physician employment status, legal organization of practices, and income distribution methods; and
- emerging practice arrangements.

The report is based on the 1983 Socioeconomic Monitoring System (SMS) core survey and the 1975 AMA Periodic Survey of Physicians.

Distribution of Physicians by Practice Size

As shown in Table 1, the average number of physicians per practice increased over the period from 1975 to 1983. In 1975, 54.2 percent of physicians were solo practitioners compared with 16.8 percent in practices of five or more physicians. By 1983, the share of physicians in solo practice declined to 48.9 percent while the share of physicians in practices of five or more physicians increased to 22.7 percent. The share of two physician practices decreased, but the percentage of three and four physician practices increased.

The shift in the size-distribution of physician practices may be attributable to several factors. Advances in medical technology may require larger group practices to adequately utilize various types of practice capital. Physicians may be attempting to reduce their individual

Table 1

DISTRIBUTION OF PHYSICIANS BY SIZE OF PRACTICE, 1975 AND 1983

Size of Practice *Number of Physicians*	Percent of Physicians* *1975*	 *1983*
One	54.2%	48.9%
Two	14.1	12.5
3-4	15.0	15.7
5-7	6.3	8.6
8-25	6.0	8.8
More than 25	4.5	5.3

*Excludes physicians employed by hosptials and government agencies.

Table 2

PHYSICIAN EMPLOYMENT STATUS, 1983

	*Self-Employed**	*Hospital Employee*	*Government Employee*	*Other Employee*
ALL PHYSICIANS	77%	9%	2%	12%
Specialty				
General/Family Practice	83	4	2	11
Medical Specialties	72	10	3	15
Surgical Specialties	87	3	1	9
Other Specialties	68	16	4	12
Physician Age				
Less than 36 years	61	11	2	26
36 to 45 years	77	10	3	10
46 to 55 years	80	8	3	9
More than 56 years	81	7	2	10

*Includes physicians who are sole or part owners of their main practice.

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

exposure to financial risk through larger group practices. The shift to larger group practices may also reflect the increasing attractiveness to physicians of alternatives to investment in medical practice.

Physician Employment

Practice opportunities for physicians have changed as a result of increasing competition. In 1983, 77 percent of physicians were self-employed, while 23 percent were employees of hospitals, state and local governments, and other institutions, as shown in Table 2. Self-employment was highest among surgical specialties and lowest among medical and "other" specialties, including pathology (54%), pediatrics (67%) and radiology (71%). With respect to physician age, young physicians were less likely to be self-employed than older physicians. This suggests that for many young physicians, the costs of purchasing or establishing a new practice may exceed their ability to borrow through capital markets, particularly in the presence of debts from medical education.

Legal Forms of Organization

Physicians have responded to the changing medical practice environment by altering the legal forms of organization of their practices. In 1983, 30 percent of physicians had their main practices in sole proprietorships, 9 percent in partnerships, and 54 percent in professional corporations. Less than one percent of physicians had their main practice in investor-owned for-profit organizations.

As reflected in Table 3, the share of physicians in professional corporations increased among all specialties from 1975 to 1983, with the largest rate of growth among general/family practice practitioners. The growth of professional corporations may be explained by the growth in physician supply, increases in unemployment, and cutbacks in government health insurance programs over this period. Physicians may cope with the increased financial risk of medical practice brought about by these changes by limiting their financial liability through incorporation. Potential tax advantages associated with professional corporations have reinforced this tendency over this period, but tax motivations may be less important in the future as a result of recent changes in the tax code.

Methods of Income Distribution in Non-Solo Practices

As the share of physicians in solo practice declines, the choice of the method by which practice proceeds are distributed to the individual physicians in group practices becomes increasingly important. In 1983, the most common form of compensation for non-solo physicians was a practice salary, followed by fee-for-service, as shown in Table 4. Among specialties, 41 percent of general/family practice physicians were compensated on the basis of fee-for-service, compared with 31 percent for medical specialties. Young physicians were less likely to be compensated on the basis of fee-for-service than older physicians. Other methods of income distribution, such as a percent of net or gross billings, were less common.

Emerging Practice Arrangements

In an effort to attract and retain patients, some physicians have begun to provide various types of medical services in new types of practice settings. In addition to increased convenience for patients, certain medical services may be provided in these settings at a cost savings over traditional medical care facilities. Among the new types of practice settings are free-standing primary care or emergency centers operated either by hospitals or by chains that have centers operating under the same name. Of the physicians responding to the 1983 SMS core

Table 3

PERCENT OF PHYSICIANS IN PROFESSIONAL CORPORATIONS 1975 and 1983

	1975	*1983*
ALL PHYSICIANS*	31%	54%
Specialty		
General/Family Practice	24	39
Medical Specialties	33	47
Surgical Specialties	48	64
Other Specialties	43	60

*Excludes physicians employed by hospitals and government agencies.

Table 4

METHODS OF PRACTICE INCOME DISTRIBUTION FOR NON-SOLO PHYSICIANS, 1983

		Percent	*Percent*		
	Fee-For Service	*Salary*	*of Net Billings*	*of Gross Billings*	*Other*
ALL PHYSICIANS*	34%	52%	6%	5%	3%
Specialty					
General/Family Practice	41	43	7	7	2
Medical Specialties	31	56	6	4	3
Surgical Specialties	37	49	7	4	3
Other Specialties	32	55	4	5	5
Physician Age					
Less than 36 years	26	58	6	6	4
36 to 45 years	34	52	6	5	3
46 to 55 years	36	50	5	4	4
More than 56 years	39	48	6	5	2

*Excludes solo physicians, and physicians employed by hospitals and government agencies.

survey, 57 percent indicated that at least one of these types of centers existed in their area of practice. Overall, 9 percent indicated that they provide some care at such centers. However, physicians providing care at such centers spent only a small portion of their total patient care hours (an average of 13 hours per week) practicing at these facilities.

With respect to the ownership of these free-standing centers, 50 percent of the physicians indicated that the free-standing facility in which they provided care was operated by a not-for-profit hosptial, 13 percent indicated that it was operated by a physician-owned chain of centers, 10 percent indicated it was operated by a non-physician investor-owned chain, and 9 percent indicated the center was operated by a for-profit hospital. This suggests that despite a significant presence of investor-owned for-profit facilities, these new types of practice settings are predominantly operated by not-for-profit hospitals.

The 1983 SMS core data contains a representative sample of 3,951 nonfederal patient care physicians, excluding residents. The SMS survey achieved a response rate of 61.8 percent.

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Nitroglycerin Patches

THE MEDICAL LETTER

When The Medical Letter first evaluated nitroglycerin patches *(Nitrodisc*—Searle; *Nitro-Dur*—Key; *Transderm-Nitro*—Ciba) for prevention and treatment of angina pectoris (Vol. 24, p 35, 1982), pharmacokinetic data looked promising, but clinical experience was limited. Now more data are available.

The Patches—Transdermal nitroglycerin products, which look like adhesive bandages, are available in different sizes, as shown in the table below. The terminology used to describe the various patches is confusing, because the *Nitrodisc* and *Transderm-Nitro* prodcts are "5" or "10" when they are designed to deliver 5 or 10 mg of nitroglycerin in 24 hours, but the *Nitro-Dur* patch is named for the size (in cm^2)of the patch. Individual patients vary markedly in their absorption of nitroglycerin from the skin; the amounts "delivered" in the table are average figures.

The rate of delivery of the drug from the inner surface of the patches is controlled either by dispersing it in a solid, nitroglycerin-impregnated polymer *(Nitrodisc)*, incorporating it in a gel-like matrix *(Nitro-Dur)*, or placing a semipermeable membrane between the drug reservoir and the skin *(Transderm-Nitro)*. Although often applied over the precordium, transdermal patches can be attached to any hairless area of the skin, except the distal portions of the extremities.

Clinical Trials—One clinical study examined the exercise tolerance of patients with exertional angina using a bicycle ergometer. In a double-blind controlled trial, nitroglycerin patches releasing an average of 9.4 mg in 24 hours produced only a slight increase in exercise tolerance in seven patients four and eight hours after application; at 24 hours, exercise tolerance with transdermal nitroglycerin was nearly identical to that with placebo. When sublingual nitroglycerin was used as a positive control, exercise tolerance increased markedly. In another trial, maximal tolerated doses of transdermal nitroglycerin (22 to 25 mg per day) in eight patients produced a statistically significant increase in exercise tolerance at four and eight hours, but not at 24 hours. Even at four and eight hours, these maximal doses of transdermal nitroglycerin were much less effective than sublingual nitroglycerin (N Reichek et al, Am J Cardiol, 54:1, July 1, 1984).

Another study found that the length of time 11 patients could walk on a treadmill before developing angina was increased at two and four hours with large doses of transdermal nitroglycerin, but even patches delivering 30 mg of the drug per day did not increase exercise tolerance at 24 hours. After using patches delivering 15 mg per day for two weeks, the beneficial effects at two and four hours were gone (JO Parker and H-L Fung, cited by J Abrams, Am J Cardiol, 54:220, July 1, 1984).

A randomized double-blind, double-crossover trial used daily diaries, exercise tests, and Holter monitors for four one-week periods to assess the anti-anginal ef-

Product	*Patch Size*	*Average Amount of Drug Delivered in 24 Hrs*	*Cost**
Nitro-Dur5 (Key)	5 sq cm	2.5 mg	$ 5.85
Transderm-Nitro 2.5 (Ciba)	5 sq cm	2.5 mg	6.44
Nitrodisc 5 (Searle)	8 sq cm	5.0 mg	6.30
Nitro-Dur 10 (Key)	10 sq cm	5.0 mg	6.07
Transderm-Nitro 5 (Ciba)	10 sq cm	5.0 mg	6.72
Nitro-Dur 15 (Key)	15 sq cm	7.5 mg	6.52
Nitrodisc 10 (Searle)	16 sq cm	10.0 mg	6.72
Nitro-Dur 20 (Key)	20 sq cm	10.0 mg	6.72
Transderm-Nitro 10 (Ciba)	20 sq cm	10.0 mg	7.39
Transderm-Nitro 15 (Ciba)	30 sq cm	15.0 mg	8.14

*Cost to the pharmacist for one patch daily for seven days, according to manufacturers' listings in *Drug Topics Red Book* 1984 and June *Update*.

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fect of 5 mg per day of transdermal nitroglycerin in 10 patients. There was no difference between drug and placebo in the number of anginal attacks; episodes of ST segment depression were slightly less with the drug during the first crossover period, but the differences were not statistically significant. During the second crossover period, no differences between nitroglycerin and placebo were detected (PA Crean et al, Circulation, 68:III-405, 1983).

Other controlled studies, however, have reported that nitroglycerin patches are effective for 24 hours or longer. Decreased freguency, severity and duration of anginal attacks and ST segment depression were observed during treadmill tests in 13 patients treated with 5 mg/24 hours for 14 days in a double-blind crossover trial (AJ Georgopoulos et al, Eur J Clin Pharmacol, 22:481, 1982). In a crossover trial with a dose of 10 mg or more per day in 20 patients, exercise time to anginal threshold increased significantly at 2 hours and at 26 hours in comparison to placebo (R Thompson, Circulation, 68:III-407, 1983). In another double-blind trial, 10 to 20 mg per day of nitroglycerin transdermally was effective in prolonging exercise tolerance in six of eight patients over 26 hours (RH Thompson, Angiology, 34:23, 1981; Cardiovasc Rev Rep, 4:91, 1983).

Nitroglycerin Ointment—Whether continued use of nitroglycerin ointment, the least costly formulation of topical nitroglycerin, also could produce tolerance to the drug is not known; one study found loss of effectiveness of nitroglycerin ointment after four weeks of tid treatment (AD Struthers et al, Br J Clin Pharmacol, 14:843, 1982), but another study found sustained effectiveness when the drug was given tid over eight to 12 weeks (N Reichek et al, Circulation, 50:348, 1974). Possibly intermittent treatment with nitrate-free intervals can delay or prevent development of tolerance (JO Parker et al, Circulation, 68:1074, 1983).

Conclusion—Some recent studies suggest that tolerance to the effects of nitroglycerin patches can develop rapidly, with little activity 24 hours after application and, with continued use, decreased anti-anginal effects in the first eight hours. Even fairly high doses of transdermal nitroglycerin appear to be less effective than sublingual nitroglycerin.

Beta-Adrenergic Blockers For Anxiety

Propranolol *(Inderal)* is approved by the US Food and Drug Administration (FDA) for treatment of hypertension, angina pectoris, cardiac arrhythmias, migraine, hypertrophic subaortic stenosis, pheochromocytoma, and reducing the risk of mortality in survivors of myocardial infarction. Propranolol and other beta-adrenergic receptor blocking agents have also been used for treatment of chronic anxiety (non-specific or associated with illness), panic attacks, and debilitating anxiety experienced by healthy people in stressful situations (WH Frishman, in WH Frishman, ed, *Clinical Pharmacology of the β-Adrenoceptor Blocking Drugs,* 2nd ed, Norwalk:Appleton-Century-Crofts, 1984, p 479).

Clinical Trials In Anxiety States—Several reports have suggested that beta blockers can decrease tremor, sweating, tachycardia, palpitation, and other physical symptoms associated with anxiety (MM Suzman, Postgrad Med J, 47 Suppl:104, 1971; PJ Tyrer, Drugs, 20:300, 1980; R Noyes, Jr, Psychosomatics, 23:155, 1982). Other drugs are more effective, however, for patients with chronic anxiety. A six-week double-blind trial found greater improvement in anxiety with 10 mg tid of chlordiazepoxide (*Librium;* and others) than with 30 mg tid of propranolol in 105 patients with acute and chronic anxiety neuroses, but the difference was not statistically significant (D Wheatley, Br J Psychiatry, 115:1411, 1969). A controlled crossover trial in 12 chronically anxious psychiatric outpatients found diazepam more effective in relieving anxiety than propranolol or placebo; propranolol was more effective than placebo in patients whose anxiety symptoms were mainly somatic (PJ Tyrer and MH Lader, Br Med J, 2:14, 1974). A randomized three-week double-blind trial in 29 patients with anxiety found oxprenolol (*Trasicor* in Canada; not available in the USA) less effective than diazepam (G Johnson et al, Med J Aust, 1:909, 1976).

Tricyclic antidepressants, such as imipramine (*Tofranil;*and others), and monoamine oxidase (MAO) inhibitors, such as phenelzine *(Nardil),* are more effective than beta blockers for treatment of recurrent *panic attacks*—sudden, inexplicable feelings of extreme terror or impending doom with prominent autonomic symptoms, sometimes accompanied by agoraphobia (Am Psychiat Assoc, *Diagnostic and Statistical Manual of Mental Disorders,* 3rd ed, [DSM-III], Washington, DC:Authors, 1980; L Grunhaus et al, J Nerv Ment Dis, 169:608, 1981). In patients with this disorder, a panic attack often can be induced by an intravenous infusion of sodium lactate and prevented by giving an antidepressant before the infusion; a single intravenous infusion of propranolol did not prevent panic attacks brought on by lactate infusions in six patients with panic disorder (JM Gorman et al, Arch Gen Psychiatry, 40:1079, 1983). However, in patients with functional cardiac illness associated with excessive beta-adrenergic activity, some studies have suggested that beta blockers might be helpful (DJ Greenblatt and RI Shader, in DF Klein and R Gittelman-Klein, eds, *Progress in Psychiatric Drug Treatment,* New York:Brunner/Mazel, 1975, p 1047).

Stressful Situations— A double-blind crossover trial found that 40 mg of oxprenolol taken 90 minutes before a performance decreased nervousness and tremor in 24 musicians and improved performance, especially in those most affected by nervousness (IM James et al, Lancet, 2:952, 1977). A double-blind trial in 15 musicians with a history of impaired performance due to palpitations, increased muscle tone, or tremor found that 50 to 100 mg of alprenolol (not available in the USA) 30 minutes before a concert was more effective than placebo in relieving these and other symptoms, such as uneasiness, irritability, cold clammy hands, and lack of concentration (S Lidén and C-G Gottfries, Lancet, 2:529, 1974).

Another double-blind trial in 22 string players found improved performance when they had taken 100 mg of atenolol *(Tenormin)* six and a half hours before (KA Neftel et al, Psychosom Med, 44:461, 1982). One 40-mg dose of propranolol, taken 90 minutes before performing, was similarly effective in decreasing anxiety, heart rate, and dry mouth and in improving performance in 29 musicians (CO Brantigan et al, Am J Med, 72:88, 1982). Pretreatment with 40 mg of oxprenolol in a double-blind trial decreased tachycardia, ECG changes, and plasma fatty acid elevations in 15 public speakers (P Taggart et al, 2:341, 1973). In another study, the heart rates of eight surgeons were monitored during operations; all developed tachycardia (mean rate 121), which was abolished by pretreatment with 40 mg of oxprenolol (GE Foster et al, Lancet, 1:1323, 1978).

Some studies have suggested that propranolol may decrease anxiety and improve examination performance in students who might otherwise be hampered by severe anxiety, especially those with prominent cardiovascular symptoms (C Brewer, Lancet, 2:435, 1972). In one study, 10-mg IV doses of propranolol appeared to improve performance in a learning task in elderly paid volunteers (C Eisdorfer et al, Science, 170:1327, 1970). In another trial, however, oxprenolol did not improve performance in a short-term memory test in either anxious or non-anxious volunteers (N Desai et al, Br J Clin Pharmacol, 15:197, 1983). A single dose of mepindolol (a beta blocker not available in the USA) lowered pulse rates but did not improve examination performance in two double-blind trials involving 104 students; some students who took the drug complained of dizziness, fatigue, and headache (P Krope et al, Pharmacopsychiatria, 15:41, 1982).

Adverse Effects—Propranolol is usually well tolerated but is potentially dangerous in patients with heart disease or asthma, since even low doses can cause bradycardia, congestive failure, or life-threatening bronchospasm (Medical Letter, 25:26, 1983; 24:44, 1982). Fatigue, depression, nightmares, and impaired sexual function are fairly common adverse effects of continued use. Depression and other CNS symptoms might be less freguent with a beta blocker such as atenolol that reaches the central nervous system only in low concentrations (GN McNeil et al, Am J Psychiatry, 139:1187, 1982). Propranolol can cause peripheral arterial insufficiency and is contraindicated in patients with Raynaud's phenomenon. It masks most of the signs of hypoglycemia in diabetics and may decrease cardiac responsivity during general anesthesia. Rebound phenomena, including angina pectoris and myocardial infarction, have been reported with sudden discontinuation of the drug after prolonged use.

Beta-adrenergic blockers can interact with a large number of other drugs, resulting in increased or decreased effects or increased toxicity of one or both drugs, hypotension, cardiac failure, or hypertensive episodes (*The Medical Letter Handbook of Drug Interactions,* 1983 and vol 26, p 11, Feb 3, 1984).

Conclusion—Propranolol and other beta blockers are less effective than benzodiazepines for treatment of most patients with chronic anxiety and less effective than antidepressants or monoamine oxidase (MAO) inhibitors for treatment of panic disorders. A single dose of a beta blocker can decrease anxiety and improve performance in some people who suffer disabling symptoms in stressful situations.

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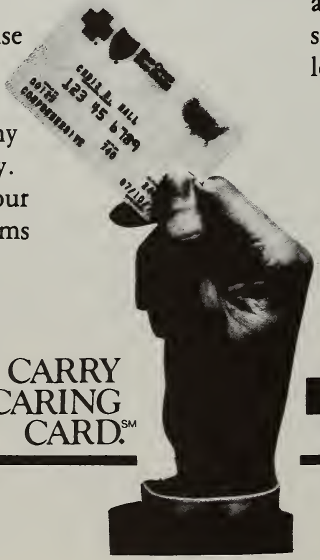

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Editorials

Insurance Coverage for Organ Transplantation

Insurance coverage for organ transplantation is being much debated. The humanitarian impulse to fund all healthcare is strong. Nevertheless, healthcare programs can no longer be judged each alone, because for every something added, another is vanishing.

If the society buys all desired healthcare, other uses for money will be squeezed out. Already, one of every nine dollars of Gross National Product goes to healthcare. If the remaining eight of nine are wanted for other goods (housing, food, recreation, national defense, education, environment, and voluntary charities, for example), the healthcare sector cannot grow. The share of wealth it now uses can be sliced up in different ways, but not increased.

If organ transplantation were included under standard healthcare insurance policies, the amount spent on it would grow rapidly. Estimates of the increase vary because no one knows how many persons a year would be treated. Taking heart transplantation as one example, the *first year* cost of a well insured program has been estimated at between 200 million and 3.2 billion dollars, depending upon whether 2,000 or 30,000 transplants were done.

It would be wise to bet on the high side. The demand for high technology care explodes when patient, physician, and hospital are all excused from considering the financial implications. More and more patients are found when there is money to pay for procedures.

This "woodwork effect" is seen in treatment of kidney disease, including hemodialysis and kidney transplantation, which was fully funded in 1973 via Public Law 92-603. Congress was told at the time that the program cost would rise very slowly, never totalling more than one or two billion dollars per year at some distant future time. However, the program cost 2 billion dollars in 1983 and is now projected to build to 6 billion annually by 1992. Generous funding calls forth high technology care even for patients failing in multiple physical systems and who are in the late stages of other terminal disease.

Whether we want to encourage vast and unpredictable increases in organ transplantation depends on what other healthcare we would willingly give up. Guesses about tomorrow's cuts come from experience with belt-tightening today. Cuts are everywhere, in both public and private sectors.

Specifically, annual federal support for maternal care has shrunk by $13 million. Medicaid funding of vitamin supplements for pregnant women has disappeared in Tennessee. Davidson County (Nashville) foresaw the need to charge a copayment of 75 cents for each drug prescription filled for the medically indigent, and withdrew this requirement (temporarily?) only after protest. The elderly and/or poor generally have lost benefits through: steady increases in Medicare patient cost-sharing, so Part A and B deductibles are now $365 and $75, respectively; a "suggested" charge for outpatient visits to municipal hospitals; fewer prescriptions per month filled free and lower limits on paid hospital days through Medicaid; and a diagnostic related group (DRG) method of Medicare reimbursement to hospitals. DRGs may (or may not) have a negative impact on care, but they do unquestionably shorten hospital stays.

Employees in both private and public sectors have also seen erosion of their healthcare benefits. Employers' healthcare costs have grown as much as 40 percent per year, and still are increasing 18 percent annually on average. There are demands to share the burden, so employees face: higher annual deductibles before insurance covers bills, larger patient copayments on each healthcare event, less coverage for their families, and cuts in types of healthcare covered.

All this presupposes trade-offs within healthcare. Now consider the alternative, allowing healthcare to take more than the present 11 percent of the Gross National Product. That is, move into the eight of nine dollars now

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Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

used for other goods and services.

When healthcare is a cost of doing business, increases not absorbed by labor and owners are passed on as higher prices. That price rise may not be small: General Motors estimates that healthcare accounts for $600 of their cost in producing every new car; more than the cost of steel for that car. There may also be tradeoffs between employment security, benefits, and wages, because some employers find that benefits including healthcare amount to 25 percent of labor costs.

In the public sector, of course, tax-payors pay for government spending. If taxes are not enough, the deficit climbs and so, eventually, do interest rates. Home mortgage borrowers, any buyer using credit, and consumers who pay prices inflated by the cost of credit pay again.

Forty-one percent of national spending on health is channelled through government at some level. There already are federal and state subsidies specifically for organ transplantation. The national 1984 Organ Procurement and Transplantation Act authorizes $25 million over three years to assist in matching donors and recipients; and in some states including Tennessee, Medicaid will pay for Cyclosporan-A, at $8000 per patient-year of survival. Nevertheless, experience with the kidney program probably will deter government from wholesale funding. Once burned, twice shy.

Whether or not organ transplantation is added to standard coverage in private healthcare insurance packages, this will not be the last promising, life-saving technology that tempts us. Other expensive procedures are around the corner. Whatever might find a buyer will be developed, even when effectiveness is uncertain.

A "yes or no" option no longer serves for making healthcare choices; it is too hard to deny the particular sufferer. An "either/ or" model is better because it is a reminder that that there are many losers for every big winner. Basic healthcare needs today and tomorrow could be sacrificed if organ transplantation is included under standard health insurance coverage.

An alternative to standard coverage is to make new, high technology coverage optional (and priced at projected cost), just as cancer care insurance above ordinary policy limits is available for those who want it and will pay. Above some standard of healthcare that the society can afford for all, perhaps individuals may have to take responsibility for healthcare insurance that suits both their pocketbooks and their wish to be treated at any physical and financial cost.

Virginia Abernethy, Ph.D.

Professor of Psychiatry (Anthropology),
Vanderbilt University School of Medicine,
Nashville, TN

Compensating for Vaccine Injuries

In Senate hearings last summer, parents whose children suffered injury from a vaccine expressed bitterness because immunizations are mandatory for school attendance and because physicians had not warned them of possible adverse effects.

The public cannot necessarily be expected to understand the logic of "calculated risk," and that *not* providing the immunizations would expose children to much greater risk. Proportionately, a far greater number of those un-immunized against pertussis suffer neurological impairment from the disease itself and, if it strikes in the first year of life, death is common.

The incidence of brain damage from the pertussis component in DPT is estimated to be about three cases per million doses administered; with the measles vaccine one case per million is adversely affected. Paralytic polio follows in one case per three million oral doses.

The figures are clearly in favor of immunizations, yet a psychological predicament exists that is not easy to solve: anger and feelings of guilt following serious injury after an immunization given at parents' request are more intense and difficult to cope with than if the natural disease were to strike and leave a child handicapped. In practice, logic and emotion are at odds.

Because of the problems linked to immunization risks, the American Medical Association established a Commission on Vaccine Injury Compensation. The report of this Commission is of importance to practitioners and is reprinted in this issue of *Connecticut Medicine.*

Since the most likely of the vaccines to produce damage is the pertussis component of the DPT, physicians should be reminded *not* to give the whooping cough vaccine under these circumstances:

1. after the age of six years
2. during any acute illness
3. if there is a personal or family history of neurological disease, and
4. if there was more than a mild reaction to a previous pertussis vaccine: it is important to ask about past reactions such as fever, allergies, screaming, somnolence, convulsions or any other neurologic symptoms.

It is advisable to tell parents of the risks of *both* choices: immunizations provided, and immunizations omitted—which may expose a child to the greater risk of acquiring the natural disease. Some physicians request signed informed consent agreements. It is appropriate to obtain a parent's signature when immunizations are offered and refused.

There is urgent need for a sensible procedure that would compensate those who are damaged from a vaccine. The issue is too important to leave to the slow, haphazard and absurdly expensive litigation process.

Hans H. Neumann M.D.

Wilton, CT

The President's Page

The Enemy

The inimitable Pogo of comic strip fame once said "We have met the enemy and they is us."

In my years of medical political activity at a county level, then the state as councillor and later as an officer of CSMS, I have been a keen observer of the machinations of the varied groups involved in political activity for a long period of time. I have observed the interaction between people and organizations which make up CSMS and feel capable of making some comments about physicians based on these observations, which are not all flattering.

I have seen doctors argue eloquently and vehemently on principle at times, yet in another situation espouse pure self interest. I have seen county oppose county for no good reason other than an elitist one, namely, "we can do it better." The same opposition has occurred because one county has formulated an approach to a problem which may not be in keeping with the thoughts of one or more dominent members of a County Board of Directors. There seems to be a distrust or kind of paranoia which exists in certain parts of our state as far as actions of other parts of the state are concerned. This attitude at times pervades even single communities. As president of my county association I was once accused of being a socialist because I felt physicians should be responsible for their actions, should police themselves and should get a fair fee for services rendered rather than attempting to get whatever the traffic will bear. A personal friend who informed me of my "socialistic reputation" had many laughs because he knew me as strictly a private practitioner.

Tort reform is the current rage because the high premiums for malpractice insurance as well as the high cost of defensive medicine are significantly increasing the price of medical care which industry, government and individuals must pay in order to preserve our system of health care. CSMS has been deeply involved in Tort reform for many years and has made some gains, yet various county organizations as well as sections of CSMS go out on their own in attempting to effect legislation without coordinating their activities with anyone. In addition, other groups spring up seeking funds from physicians even though they are not sanctioned by any county or by your state society. Official and officious sounding letters are sent out to doctors suggesting that these organizations will accomplish great things.

One of the major accomplishments of our state society has been the establishment of CMIC, our own insurance company. The seeds for this organization were planted in the early seventies, before the malpractice crisis and bore fruit in 1981 when CSMS obtained an insurance charter. Factors then arose which prevented implementation of our own malpractice company. The principle factor was financial in that a company seeking to write business in our state undercut the major insuror and made implementation of CMIC difficult, if not impossible. Short term gain was offered and accepted by us. What happened to that gain is now history and I hope it will not be repeated.

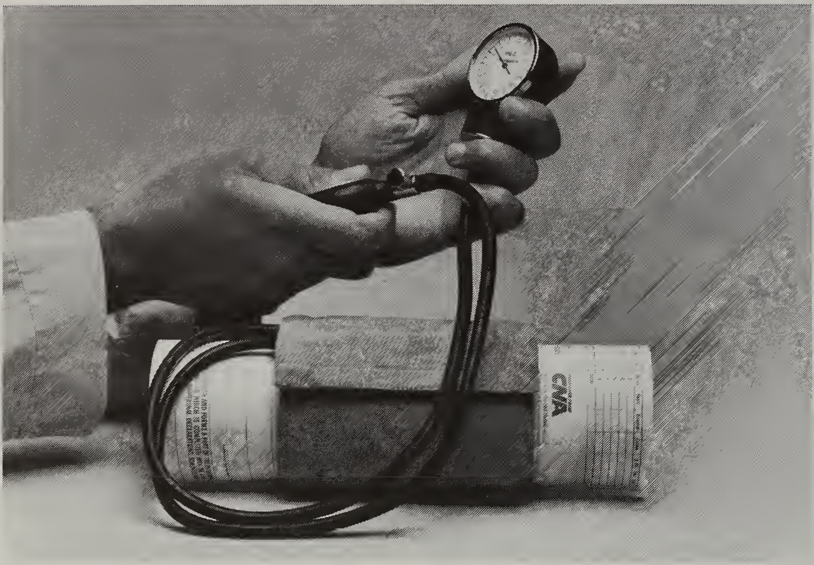
In spite of the fact that we now have a viable professional liability insurance company in Connecticut, there is still a great deal of rumor and innuendo which periodically arises and tends to fire the coals of paranoia among some society members. At times one gets the feeling that there are physicians or employees of state medical organizations who have a vested interest in seeing that *our* insurance company fails. Instead of supporting the concept and early success of CMIC I find it extremely disconcerting to hear that physicians who are or have been active in medical politics are gloating over every problem CMIC encounters, regardless of its importance.

I think it's time for all Connecticut physicians to look at facts and support them so that we can at least have a semblance of unity. We will never accomplish anything if all eight counties go off in separate directions, without guidance or coordination, thinking they will accomplish what, at best, is extremely difficult, and by so doing, emerge as heroes. If this attitude persists in a state as small as ours, then we surely will have met the enemy and they will be us. If this occurs, the only one's who will suffer will be our patients and "us."

Joseph S. Sadowski, M.D.
President

If you could examine professional liability insurance the way you examine your patients…

the choice would be clear.



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Reflections on Medicine

The Immortal Germ Plasm

ROBERT U. MASSEY, M.D.

"If respiratory motions and circulation could be maintained indefinitely even the metazoa might be found to be immortal." Jacques Loeb (1912).

This baleful speculation appeared in a footnote in Loeb's "The Mechanistic Conception of Life;" he observed that Weismann had shown that infusorians or unicellicular organisms in general are immortal, and "that all other organisms *with the exception of their germ plasm* (italics mine) are mortal."

August Weismann, whose work prefigured most of modern genetics, was born in 1834 in Frankfurt am Main. He had early acquired from his music teacher an intense interest in butterfly collecting; his piano and his collection remained sources of pleasure for him throughout his long and brilliant scientific career, a career now little remembered since his death in 1914.

Weismann's father, certain that neither devotion to natural science nor accomplishment at the piano would provide an adequate living, urged him to study medicine. He took his degree at Göttingen in 1856 with a prize dissertation on the origin of hippuric acid in the urine of herbivores; he practiced in Frankfurt for a few years but returned to zoology, to his experimental work, supporting himself meanwhile as physician to the family of the Austrian Archduke Stephan in the castle at Schaumburg. In 1863 he left the practice of medicine to join the faculty at the University of Freiburg as *Privatdozent* in zoology and anatomy; in 1874 he was appointed to the chair in zoology, the first to hold that position. Already he had made important microscopic discoveries on the structure of muscle, and was the first to describe the branching cells of cardiac muscle (1861); he had published original work on insect metamorphosis, but was forced to abandon the microscope, and even reading, because of sudden blindness in his left eye.

Meanwhile he had become a vigorous supporter of Darwin's theory of evolution through natural selection, and was even more persuaded of the full sufficiency of natural selection to explain the origin of species than Darwin himself. He saw clearly, however, that a better theory of inheritance than Darwin's *pangenesis* was needed if natural selection was to rest upon firm theoretical ground.

His partial blindness which precluded further work at the microscope provided the opportunity for speculation, and he turned his attention to evolutionary theory and the nature of inheritance. In time he recovered his eyesight sufficiently to do work on the origin of the germ cells in the Hydromedusa, but was afflicted again in 1884 with recurrence of retinal disease in his left eye. Shortly thereafter, one hundred years ago this year, he published in one of his essays on heredity his remarkable assertion of the continuity of what he called the germ plasm: "—a continuous and distinct germ track coursed its way through the life history of the individual, and since it passed to the next generation, it alone survived the death of the somatic cells." Hence, if the germ plasm were potentially immortal there could surely be no inheritance of acquired characteristics. He further asserted that all genetic material was in the cell nucleus.

Darwin continued to waver between soft and hard inheritance, and could not abandon the notion that use and disuse might be reflected in genetic descent and that gemmules circulating from all parts of the body to the gametes could determine the transmission even of acquired characteristics. The Lamarckians were again strong in the last decades of the century, and it was not until after the rediscovery of Mendel that hard, non-blending inheritance was generally accepted. Weismann was more Darwinian even than Darwin. In fact, without knowing about genes and DNA—his particle was the biophore—his guesses were mostly right. One mistake was his choice of unequal cell division in the developing organism rather than activation and deactivation of the "biophores" or genes, though he had clearly considered the correct alternative and rejected it.

Human gene therapy is now about to begin, but only on cells of the mortal *soma.* The "continuity of the germ plasm," its potential for immortality, will continue to inhibit therapeutic alteration of germ cells.

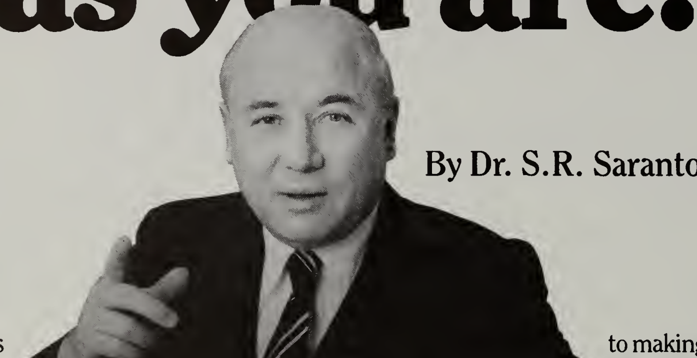
Weismann the physician and zoologist is rarely mentioned today; his work lies buried deep in the foundations of modern biology; yet his "remarkable theory—in a single sweep explained the diverse biological phenomena of heredity, development, regeneration, sexual reproduction, mitotic division, and Darwin's theory of evolution by natural selection."[1] A colleague and student described him as "one of the greatest and best men I have ever known."[2]

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

REFERENCES

1. Churchill FB: August Weismann and a Break from Tradition. Jour Hist of Biology 1:91, 1968.
2. Petnunkevitch A: August Weismann, Personal Reminiscences. Jour Hist of Med 18:20-35, 1963.

"Why your investments aren't as successful as you are."



By Dr. S.R. Sarantos

Face it. Few problems are as complex as the management of your practice, money and taxes. And few health care practitioners have the extensive specialized expertise necessary for success in precisely these disciplines. Expertise which is vital to achieving financial growth, and, ultimately, independence.

As one of the health care practitioners who has been fortunate enough to gain these crucial financial skills, I'd like to share a few observations on why so many otherwise successful practitioners don't have similar success when it comes to their investments.

Strategies to make your earnings grow

A successful practice alone is not enough to guarantee your financial independence. That requires a careful balance of prudent, disciplined tax planning and professional management of your retirement assets.

Too many of you have relied far too much on the stock market...and paid the price for its unpredictability. Why assume such risk–when you can pursue a conservative, non-stock market approach that provides for a reliable, real rate of return? A diversified portfolio based on short-term guaranteed investment vehicles, as well as real estate investments designed specifically for retirement plans, can satisfy both your immediate and future financial needs.

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193rd ANNUAL MEETING
OF THE
CONNECTICUT STATE MEDICAL SOCIETY
PARK PLAZA HOTEL, NEW HAVEN
Thursday, May 9, 1985

GENERAL SCIENTIFIC PROGRAM

MORNING SESSION

8:15 REGISTRATION—Mezzanine

8:30-10:00 MEETINGS OF SECTIONS OF THE SOCIETY

10:00 INTERMISSION TO VISIT EXHIBITS

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
President, Connecticut State Medical Society
Presiding: James D. Kenney, M.D., New Haven
SYMPOSIUM ON COMPUTERS IN MEDICINE

10:25 INTRODUCTORY REMARKS
JAMES D. KENNEY, M.D., NEW HAVEN; Associate Dean for Graduate and Continuing Education, Yale University School of Medicine

10:30 COMPUTERS IN MEDICINE: AN OVERVIEW
DAVID STAGG, PH.D., NEW HAVEN; Director, Bio-Medical Computer Unit, Yale University School of Medicine

11:00 COMPUTERS IN DIAGNOSTIC IMAGING
JOHN C. GORE, PH.D., NEW HAVEN; Associate Professor, Diagnostic Radiology, Yale University School of Medicine

11:30 COMPUTERS IN HOSPITAL MANAGEMENT: PATIENTS, DOCTORS, INFORMATION AND RESOURCES
ROBERT T. SADOCK, M.D., NEW HAVEN; Physician Administrative Associate, Yale-New Haven Hospital

12:00 COMPUTERS IN PATIENT MANAGEMENT: AN EXAMPLE IN ANESTHESIOLOGY
PERRY L. MILLER, M.D., PH.D., NEW HAVEN; Assistant Professor of Anesthesiology, Yale University School of Medicine

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

AFTERNOON SESSION

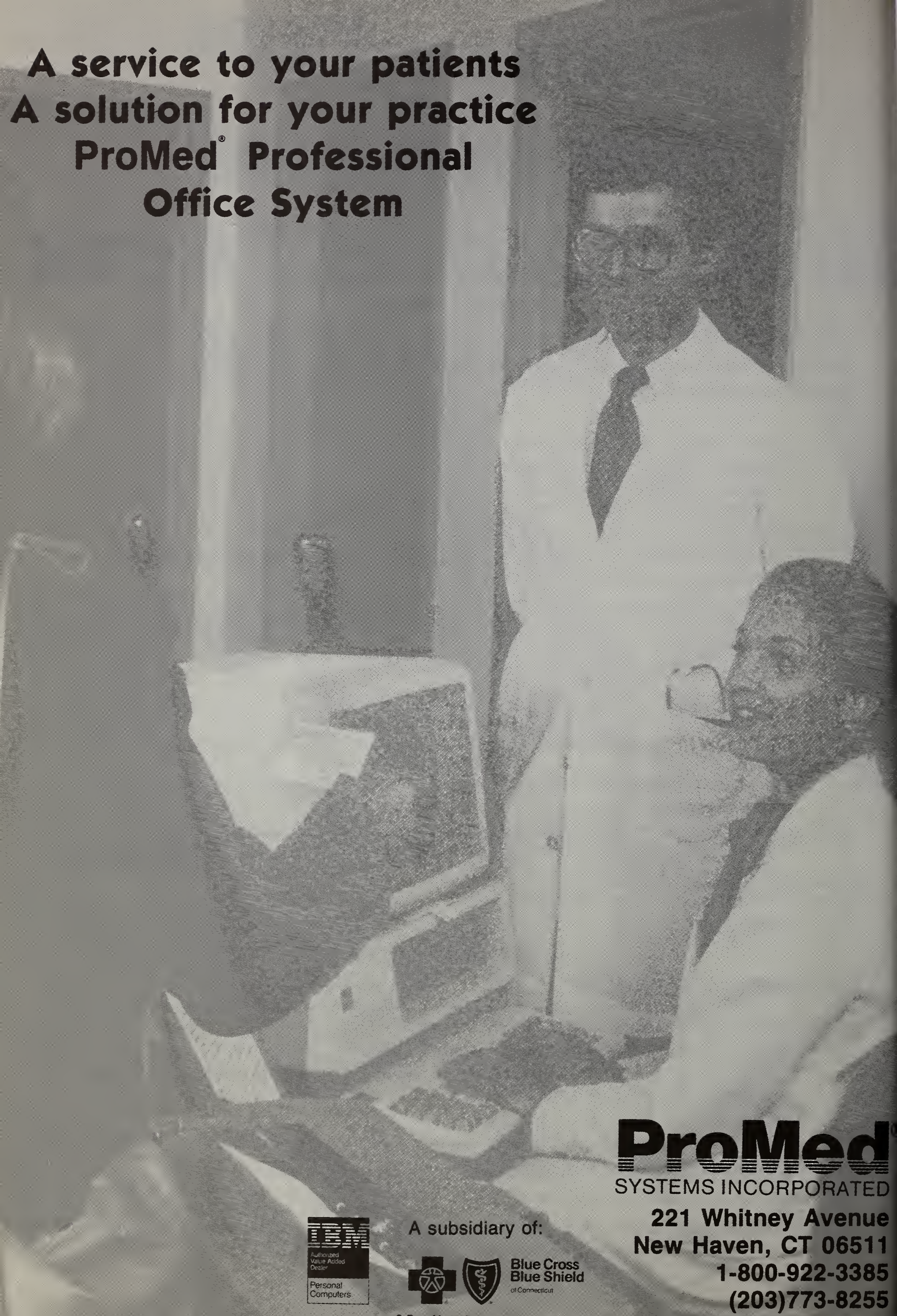
2:00 WHAT'S NEW IN DEMENTIA
ROBERT E. HARBAUGH, M.D., NEW HAMPSHIRE; Department of Neurosurgery, Dartmouth Medical School, Mary Hitchcock Clinic, Hanover

2:30 CLINICAL APPLICATIONS OF GENETIC ENGINEERING
SALLY SCHULMAN, M.D., FARMINGTON; Department of Pedicatrics and Human Genetics, University of Connecticut Health Center

3:00 AIDS: IMPLICATIONS IN YOUR PRACTICE
EILEEN HILTON, M.D., DANBURY; Department of Infectious Diseases, Danbury Hospital

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY



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CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1985 Annual Meeting of the House of Delegates will be held at the Park Plaza Hotel New Haven, commencing at 12:30 P.M. on Wednesday, May 8.

Joseph S. Sadowski, M.D., President
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

PROPOSED AMENDMENTS TO THE BYLAWS

The following proposed amendments to the Bylaws were presented to the House of Delegates on November 15, 1984 and were tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, these amendments will be published in Connecticut Medicine "on one or more occasions prior to the next meeting . . . at which meeting the amendments shall be taken off the table and acted upon by the House of Delegates."

SUBJECT: DELINQUENCY

OBJECTIVE: To change the date of dues delinquency from August 1 to April 30. This will conform with the AMA delinquency date and also satisfy the requests from some of the counties which would like an earlier delinquency date.

PROPOSED AMENDMENT: ARTICLE XII

Section 4—Delinquency (Delete underlined words, add words in capitals.)

Par. 1—An Active Member is delinquent if his dues are not paid by August first APRIL THIRTIETH of the year for which dues are prescribed and shall forfeit his active membership in the Society if he fails to pay the delinquent dues within thirty days after notice of his delinquency has been mailed to his last known address by the Executive Director of The Society. Active Members of The Society who have been dropped from the active membership roll for nonpayment of dues cannot be reinstated until such indebtedness has been discharged, but such indebtedness shall apply only to the one fiscal year of delinquency.

SUBJECT: DUTIES OF THE PRESIDENT

OBJECTIVE: TO MAKE IT POSSIBLE FOR THE PRESIDENT TO SERVE AS AN ADDITIONAL ALTERNATE DELEGATE TO THE AMA

PROPOSED AMENDMENT: ARTICLE VI

Section 8. Duties of the President (Add words in capitals).

The President shall be an ex-officio member of all committees. He shall appoint all committees not otherwise provided for in these Bylaws, subject to confirmation by the Council. He shall visit the component medical association. HE SHALL SERVE AS AN ADDITIONAL ALTERNATE DELEGATE TO THE AMA. He shall perform such other duties as the House of Delegates or the Council shall direct.

PLAN NOW TO ATTEND

Connecticut State Medical Society
193rd Annual Meeting
May 8, 9, 1985

PARK PLAZA HOTEL, NEW HAVEN

Annual Meeting of the House of Delegates
Wednesday, May 8, 1985

General Scientific Program of The Society
Thursday, May 9, 1985

PLAN NOW TO SAVE THE DATE

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Full and part-time emergency room opportunities available for qualified primary care physicians in Central CT and Windham county. For information and application contact the recruitment department at 1-800-645-4848.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

FAMILY PRACTICE/INTERNAL MEDICINE

Family Practitioner or Internist, Newington, CT, to practice medicine in a small State psychiatric hospital, ten minutes from Hartford. A 130 bed facility, accredited and certified, provides acute/intermediate psychiatric treatment. Position available April 1, 1985. Salary is commensurate with experience and training. Excellent benefit package. Connecticut license required. Send resume to Arnold W. Johnson, M.D., Chief of Professional Services, Cedarcrest Regional Hospital, 525 Russell Rd., Newington, CT 06111. AA/EEO.

Family practitioner or internist needed immediately as third MD in a Southeastern Connecticut practice. Salary on first year and partnership starting the second year. Send CV to 26 Lafayette St., Norwich, CT 06360.

INTERNAL MEDICINE

Growing, federally qualified HMO in Southwestern CT seeks BC/BE Internist. Emphasis on personalized, cost-effective, medicine. Competitive salary, comprehensive fringe benefits, teaching appointments to university-affiliated hospitals. Submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Connecticut Health Plan, 4000 Park Ave., Bridgeport, CT 06604. Telephone (203) 371-1534.

PRIMARY CARE

Physicians—Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

PRACTICE FOR SALE

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

Internal Medicine/Cardiology practice for sale; Northern Connecticut; close to Hartford and Springfield, MA. Flexible financial arrangements. Write to SALE/JR, c/o CSMS.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

June '85. Age 36. FLEX. AB elig. MD, University of Ceylon, Colombo, Sri-Lanka; Int. and Res., NY Medical College, NY, NY. Prefers solo, group, associate or institutional type practice. Write, PP/ANES., c/o CSMS.

DERMATOLOGY

Feb. '85. Licensed in Connecticut. Presently in practice. Age 35. FLEX. AB cert. MD, University of Oklahoma; Int., Hospital of St. Raphael (Med/Surg); and Res., St. Francis Hospital, Hartford (Path), Henry Ford Hospital, Detroit (Derm). Interested in clinical dermatology and will consider a part-time position. Would also consider solo, group or associate type practice in a medium to large-sized community. Write, Lawrence J. Fortier, M.D., 1350 W. Bethune Ave., Apt. 509, Detroit, MI 48202.

FAMILY PRACTICE

Aug. '85. Age 29. Nat'l bds. AB elig. MD, University of Washington, Seattle, WA. Int. and Res., Thomas Jefferson University Hospital. Prefers group type practice in a medium-sized community. Write, John K. Porter, M.D., 33 Lafayette Ave., Haddonfield, NJ 08033.

INTERNAL MEDICINE

July '85. Age 28. Nat'l bds. AB elig. MD, Rutgers Medical School; Int. and Res., Hartford Hospital, Hartford, CT. Prefers group or associate type practice. Write, Frances B. Gurtman, M.D., 38 Beacon St., Apt. B2, Hartford, CT 06105.

July '85. Age 33. Licensed in Connecticut. Presently in practice. AB elig. MD, University Autonona of Guadalajara, Mexico; Int. and Res., SUNY Downstate/Kings County Hospital (Brooklyn). Particularly, but not exclusively, interested in areas in western or central Connecticut with a group or associate type practice. Write, RKF/IM, c/o CSMS.

July '85. Age 27. Nat'l bds. AB elig. MD, Medical College of Virginia, Richmond, VA; Int. and Res., Medical University of South Carolina, Charleston, SC. Prefers group or associate type practice in a medium to larged-sized community. Write, Bruce A. Silverman, M.D., 3 Sawgrass Rd., Apt. F-1, Charleston, SC 29412.

Jan. '85. Age 29. AB elig. MD, Universidad del Caribe, Cayey, Puerto Rico; Int. and Res., St. Vincent's Medical Center. Prefers group or associate type practice. Write, Dominic F. Mazzocchi, M.D., 1231 East 89th St., Brooklyn, NY 11236.

July '85. Age 27. Nat'l bds. AB elig. MD, University of Connecticut; Int. and Res., Medical University of South Carolina. Prefers group or associate type practice in a medium to large-sized community. Write, Daniel P. George, M.D., MUH 627 SW, 171 Ashley Ave., Charleston, SC 29425.

CARDIOLOGY. July '85. Age 30. FLEX. AB cert. (IM); AB elig. (CARD). MD, University of Iowa, Iowa City, IA; Int., University of New Mexico, New Mexico; Res., University of Iowa; Fellowship, University of Minnesota. Has no preference to type of practice or size of community. Write, Rubin Maidan, M.D., 4843 Portland Ave., South, Minneapolis, MN 55417.

GASTROENTEROLOGY. July '85. Age 30. FLEX. AB cert. MD, Dublin University, Trinity College; Int., Sir Patrick Dun's Hospital; Res., Federated Dublin Hospitals and University of Nebraska Medical Center; Fellowship, Medical College of Virginia. Prefers group, associate or institutional type practice in medium to large-sized community near a medical school. Write, Michael N. Eppel, M.D., P.O. Box 8843, Richmond, VA 23225.

GASTROENTEROLOGY. July '85. Age 37. AB elig. MD, Autonomous University, Guadalajara, Mexico; Int. and Res., Lutheran Medical Center/Downstate Medical Center, Brooklyn, NY; Fellowship, University of Medicine and Dentistry of New Jersey. Prefers solo, group or associate type practice. Write, Ronald J. Cirillo, M.D., 7 Sandpiper Dr., Voorhess, NJ 08043.

GASTROENTEROLOGY. July '85. Age 31. FLEX. AB cert. MD, University of Louvain, Belgium; Int. and Res., St. Agnes Hospital, Baltimore, MD; Fellowship, University of Cincinnati, Cincinnati, OH. Prefers group or associate type practice. Write, Steven M. Samuels, M.D., 4908 David Court, Cincinnati, OH 45215.

GASTROENTEROLOGY. April '85. Age 44. Licensed in Connecticut. Presently in practice. Nat'l Bds. AB cert. MD, University of Missouri; Int., Kings County Hospital, Brooklyn, NY; Res., Kings County Hospital and University of Minnesota Hospitals; Fellowship, Hartford Hospital (Yale affiliated GI). Prefers group or associate type practice in medium to large-sized community. Wishes to purchase a practice in greater New Haven. Write, Michael A. Rosenthal, M.D., 4808 Longridge Ave., Apt. 112, Sherman Oaks, CA 91423.

GASTROENTEROLOGY. July '85. Age 31. FLEX. AB cert. (IM). AB elig. (GI). MD, Int. and Res., Baylor College of Medicine, Houston, TX; Fellowship, Georgetown University, Washington, DC. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Kenneth R. Feuer, M.D., 3120 Parkway, Cheverly, MD 20785.

GASTROENTEROLOGY. July '84. Age 31. Nat'l bds. AB cert. MD, Mt. Sinai School of Medicine; Int. and Res., Maimonides Medical Center; Fellowship, Memorial Sloan-Kettering Cancer Center. Prefers group or associate type practice in a medium to large-sized community. Write, Eliot Zimbalist, M.D., 430 East 67th St., Apt. 12-F, New York, NY 10021.

HEMATOLOGY/ONCOLOGY. July '85. Age 31. Nat'l bds. AB cert. MD, Boston University, Boston, MA; Int. and Res., Boston City Hospital; Fellowship, Massachusetts General Hospital. Prefers group or associate type practice. Write, Kert D. Sabbath, M.D., 118 Bonad Rd., Chestnut Hill, MA 02167.

HEMATOLOGY/ONCOLOGY. July '85. Age 37. Nat'l bds. AB cert. MD, Kyung Hee University, Korea; Int. and Res., St. Luke's Hospital, Bethlehem, PA; Fellowship, University of Illinois Hospital, Chicago, IL. Prefers solo, group, associate or institutional type practice in a medium to large-sized community. Write, Hoon Park, M.D., 112 W. 65th St., Westmont, IL 60559.

PULMONARY. Aug. '85. Age 32. Nat'l bds. AB cert. (IM); AB elig. (PUL). MD, Padua University, Padua, Italy; Int., Barberton Citizens Hospital, Barberton, OH; Res., Kettering Medical Center, Dayton, (IM); Fellowship, Memorial Sloan Kettering Cancer Center, NY (Critical Care). Prefers group, associate, institutional or industrial type practice. Write. Gianfranco Umberto Meduri, M.D., 430 East 67th St., Apt. 9C, New York, NY 10021.

OBSTETRICS & GYNECOLOGY

July '85. Age. 26. Nat'l bds. AB cert. MD, Hahnemann University, Philadelphia, PA; Int., St. Raphael's Hospital, New Haven, CT; Res., Danbury Hospital, Danbury, CT. Seeking to join a group or associate type practice. Write, Les A. Burns, M.D., 6 Essex Court, Brookfield, CT 06804.

OPHTHALMOLOGY

Immediately available. Presently in practice. Age 31. Nat'l bds. AB elig. MD, Tufts University, Boston, MA; Int., Faulkner Hospital, Boston; Res., Bascom Palmer Eye Institute, Miami, FL; Fellowship, Katzen Eye Group, Mercy Hospital, Baltimore, MD. Prefers solo, group, associate, institutional or hospital based type of practice in a medium to large-size community. Write, P.O. Box 23656, Baltimore, MD 21203.

PHYSICAL MEDICINE AND REHABILITATION

Feb. '85. FLEX. AB elig. M.B.B.S., Shah Medical College, Jamnagar, India; Int., Lions Hospital, Bhavnagar, India; Res., Nassau County Medical Center, East Meadow, NY (Pathology) and University of Medicine & Dentistry of New Jersey (Rehabilitation Medicine) and V.A. Medical Center, Brooklyn, NY. Prefers solo, group or institutional type practice. Write, Minaxi K. Vora, M.D., 41 E. White Terrace, Nutley, NJ 07110.

RADIOLOGY

July '85. Age 41. FLEX. AB elig. MD and Int., Kasthurba Medical College, India; Res., NY Medical College, NY; Fellowship, St. Louis City Hospital, St. Louis, MO. Prefers solo, group, associate or institutional type practice. Write, A.S. Sidharthan, M.D., 6979 Blue Water Trail, St. Louis, MO 63123.

July '85. Age 30. Presently in practice. Nat'l bds. AB elig. MD, SUNY Downstate, Brooklyn, NY; Res., Long Island College Hospital, Brooklyn, NY; Int., Nassau County Medical Center, NY; Fellowship, St. Louis University Medical Center, St. Louis, MO. Prefers general X-Ray with emphasis on CT/Ultrasound with a group, associate, institutional or industrial practice in a large-sized community. Write, Richard S. Steinberg, M.D., 3701 Lindell Blvd., Apt. 427, St. Louis, MO 63108.

SURGERY

Dec. '84. Age 31. Nat'l bds. AB elig. MD, NY Medical College, Valhalla, NY; Int., Res. and Fellowship, St. Vincent's Hospital and Medical Center of New York, NY, NY. Prefers group or associate type practice. Write, Nicholas G. Bonvicino, M.D., 130 West 12th St., Apt. 5-J, New York, NY 10011.

July '85. Age 33. Presently in practice. FLEX. MD, University of The West Indies, University Hospital of The West Indies; Int., Res. and Fellowship, Harlem Hospital Center (affiliated with Physician & Surgeons, Columbia). Prefers group, solo, or associate type practice in that order. Write, Derrick J. Martin, M.D., 13-2 Granada Crescent, White Plains, NY 10603.

July '85. Age 29. Nat'l bds. AB elig. MD, Trinity College, Dublin, Ireland; Int., Sir Patrick Duns Hospital, Ireland; Res., Washington Hospital Center, Washington, DC. Will consider any type practice. Write, Karl W. Sorenson, M.D., 6724 Conway Ave., Takoma Park, MD 20912.

July '85. Age 34. FLEX. AB elig. MD, Maulana Azad, University of Delhi, India; Int., Irwin and G.B. Pant Hospitals, New Delhi; Res., Youngstown Hospital Assoc., Youngstown, OH and Robert Packer Hospital, Sayre, PA. Prefers solo, group or associate type practice. Write, Naresh C. Nagpal, M.D., 323 A Hyaden St., Syre, PA 18840.

UROLOGY

July '85. Age 32. MD, Hospital of India; Res., Brookdale Hospital, NY; Res., University of Minnesota. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Binod Sinha, M.D., 3425 Golf View Dr., Eagan, MN 55123.

Stress Hypokalemia

DAVID P. LAULER, M.D.

ABSTRACT—Stress hypokalemia: under the influence of epinephrine an inward migration of potassium ions takes place resulting in a reduction of plasma potassium levels. Stress hypokalemia is a redistributive form of hypokalemia. It is associated with moderate to severe forms of clinical stress. The inward movement of potassium ions is predominantly a beta-2 (B2) receptor phenomenon. Beta blockers having a B2 component offer advantages over other blockers in modifying stress hypokalemia.

Introduction

Increasing attention is being focused on a new form of redistributive hypokalemia due to stress. Applications of the concept for the clinician are far reaching especially in the area of cardiovascular diseases. Stress hypokalemia refers to a transient reduction in extracellular fluid potassium concentration during periods of acute stress.[1] To date, the concept has been applied primarily to conditions involving moderate to severe stress.

During periods of acute stress, a predictable synchronized sympathetic neurostimulation of the adrenal medulla occurs resulting in an outpouring of catecholamines, predominantly epinephrine. In contrast to locally released catecholamines such as occurs at terminal fibers of sympathetic nerves, catecholamines released by the adrenal medulla surge into the circulation and function as circulating hormones. Within this context, the major action of this surge of catecholamies, occurs at beta receptor sites distributed throughout the body. The interaction of these circulating catecholamines with beta receptor sites on muscle cell membrane activates an inward migration of potassium ions with a resulting decrease in extracellular fluid potassium concentration and a simultaneous increment in intracellular potassium content. It is now known that it is the beta-2 (B2) receptor sites which respond predominantly to epinephrine and which are responsible for this phenomenon. This knowledge is based on experimental work involving isolated muscle strips,[2] the mimicking of stress hypokalemia by infusion in normal volunteers of epinephrine,[3] and by the demonstration that both beta-1/beta-2(B1B2) blockers[4] along with specific investigational beta-2(B2) blockers[5]favorably modify the phenomenon of stress hypokalemia.

Proposed Mechanism of Action

When circulating catecholamines, such as epinephrine interact with specific B2 receptor sites on the surface of cell membrane of body muscle cells a series of events rapidly takes place resulting in activation of the ATPase membrane system located on the cell membrane. The linkage between activation of these B2 receptor sites and stimulation of the ATPase system is thought to be due to the action of the second messenger, cyclic AMP. Under conditions of increasing concentration of cyclic AMP, there is enhanced activation of the ATPase system.[6] The particular membrane ATPase system involved is the sodium-potassium pump mechanism familiar to the practicing physician. With increased activation of the sodium-potassium ATPase system, the $Na^+ - K^+$ exchange pump mechanism operates to move increasing quantities of sodium ions from the interior of the cell into the interstitial (extracellular) fluid. Simultaneously with this movement of sodium ions, there is an inward migration of potassium ions, the net result being a simultaneous decrease in extracellular fluid potassium with an increase in intracellular potassium levels.

Clinical Significance

For the practicing physician, the phenomenon of stress hypokalemia focuses attention on the fact that during conditions of acute stress of a degree deficient to activate the adrenal medulla, predictably, hypokalemia

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DAVID P. LAULER, M.D., Chairman, Department of Medicine; Director of Medical Education, Lawrence and Memorial Hospitals, New London, CT; Clinical Associate Professor of Medicine, Yale University School of Medicine.

can occur due to a redistribution of potassium ions from the extracellular fluid to the intracellular fluid. The onset of this phenomenon is rapid, within minutes of the surge of catecholamines, and the duration of the phenomenon is in the range of 60 to 90 minutes following the catecholamine surge. Thus, despite the fact that the acute stress experienced by the patient may be limited to a few minutes, the resulting stress hypokalemia may be evident for hours.

Difference From Potassium Depletion

The transient redistribution which occurs under conditions of acute stress should be distinguished from conditions of potassium depletion. Potassium depletion by definition, implies that there is a significant clinical reduction in potassium stores predominantly of the intracellular variety since 98% of potassium is stored within cells. The most common cause of potassium depletion is the use of thiazide and thiazide/like diuretics. Of importance to the practicing physician is that the phenomenon of stress hypokalemia can occur in a potassium depleted patient. By way of example, consider the K^+ depleted hypertensive patient on long term thiazide therapy. Such a patient during an acute stress episode such as myocardial infarction could develop stress redistributive hypokalemia superimposed on the burden of K^+ depletion.[7] In essence, transient redistributive hypokalemia is occurring superimposed on chronic K^+ depletion.

Experimental Clinical Background

Among the earliest observations of the action of epinephrine to cause a reduction of potassium levels was that of Dr. D'Silva of Kings College, London.[8] In 1936, utilizing an infusion liver preparation he reported that with the addition of epinephrine to the perfusate, there resulted an initial slight increment in potassium levels followed by a sustained reduction. This seminal observation was followed up by Dr. Dury in 1951[9] who suggested that epinephrine was an important control mechanism for potassium homeostasis. Later experimental observations by Todd and Vick in 1971[10] further substantiated the work of the earlier investigators and set the stage for appropriate clinical investigations.

In the current era, interest in the phenomenon of stress hypokalemia was ushered in by simultaneous work performed both in this country and in Europe. In the United States, Dr. Rosa and Epstein[11] collaborated in a series of papers that have convincingly demonstrated that in man catecholamines play an important role in the dispersion of a potassium load. Beta agonists such as epinephrine facilitate dispersion of an excess potassium load and by this mechanism play a critical preventive role in minimizing the hazards of hyperkalemia. At Yale, DeFronzo and colleagues[12] in a series of papers simultaneously were reporting similar observations and focusing on the interrelationship between catecholamines and insulin as an important parallel mechanism for the orderly distribution of potassium ions across cell membranes.

During the years 1983 and 1984, clinical laboratories in Europe reported a series of elegant clinical investigations firmly establishing this form of redistributive hypokalemia as a predictable, reproducible, clinical phenomenon. Drs. Brown, Brown and Murphy[13] in 1983, reported clinical studies emphasizing acute hypokalemia resulting from the infusion of beta agonists and the ability to favorably modify this hypokalemia through treatment of volunteers with investigational, specific, B2 antagonists. Simultaneously, Struthers and Reed[14] in Glascow reported on a dramatic fall in plasma potassium levels that occurs during epinephrine infusion, which at higher infusion rates resulted in decrements of potassium levels of almost 1.0 mEq/L. These investigators also correlated the effect of epinephrine infusion on the body surface electrocardiogram noting changes in T-wave amplitude, QTc interval prolongation, and appearance of U waves.[15] They suggested that these EKG abnormalities reflected changes in the repolarization of cardiac cells and could provide the nidus for the genesis of certain cardiac arrhythmias. Meanwhile, Dr. Vincent at Erasmus University in the Netherlands, after analysis of the phenomenon of acute hypokalemia induced by infusions of isoprotenolol, compared the potassium protective ability of certain B1 blockers (atenolol) vs. B1B2 blockers (propanolol).[16] Based on these observations and keying on the fact that atenolol in doses of 100 mgs/day had minimal to no effect on catecholamine infusion induced hypokalemia, whereas propanolol a B1B2 blocker almost completely abolished the phenomenon, these investigators suggested that the K^+ – protection activity of the beta-2 component of B1B2 blockers may offer a clinical advantage over the dominant B1 blockers (Figure 1).

Potassium Control Systems

It has been known since 1924 that insulin infusions or injections cause a reduction in circulating potassium levels. It is now well established that insulin, independent of its effect on the transport of glucose across cell membranes, plays an additional independent role favoring the inward migration of potassium ions.[17] As is the case with the catecholamine control system, the insulin system has an immediate response time, and is thought to have evolved as a protective mechanism against the hazard of hyperkalemia due to ingested potassium loads. The phenomenon of insulin induced hypokalemia is well known to the practicing physician based on his clinical experience. As with catecholamine induced hypokalemia, insulin hypokalemia is a special form of redistributive hypokalemia (Figure 2).

In contrast to the rapid response times of insulin and catecholamine control systems, the control of potassium by the adrenal cortical hormone, aldosterone, is a much slower adaptative type of phenomenon.[18] The adaptive role of aldosterone in response to potassium loads takes hours to days to become fully evident.

It is to be appreciated that the flexibility of patients to appropriately respond to a threat of either potassium load or a catecholamine-induced hypokalemia revolves around a smooth intergration of all three control systems acting in parallel as synchronized independent but interrelated systems. If any of the control systems are impaired, an increased burden is placed on the unimpaired systems. For example, a diabetic with impaired pancreatic insulin release becomes more dependent on intact catecholamine and aldosterone response systems to minimize the potential for hyperkalemia. Mention should be made of the additional hazard imposed by loss of excretory route for potassium as occurs in renal failure, especially the loss of flexibility exhibited by patients with chronic renal failure. It is evident that patients with impaired insulin release and chronic renal failure are at double risk for hyperkalemia.

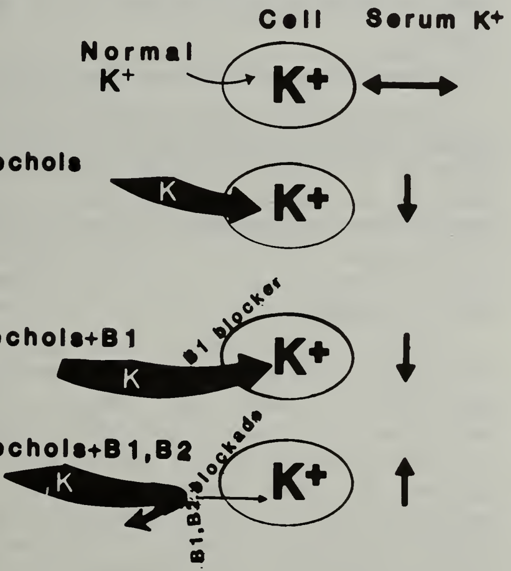

Figure 1
Effect of beta blockers on stress hypokalemia. Under conditions of acute stress, acute increases in catechols associated with decrease in serum K+ levels (top and second row). If patient pre-treated with dominant B1 blocker (eg-atenolol), hypokalemia still occurs (second row). If pre-treatment performed with B1B2 blocker (eg-proproanol), hypokalemia is minimized and slight increase in serum potassium level may be noted (bottom row).

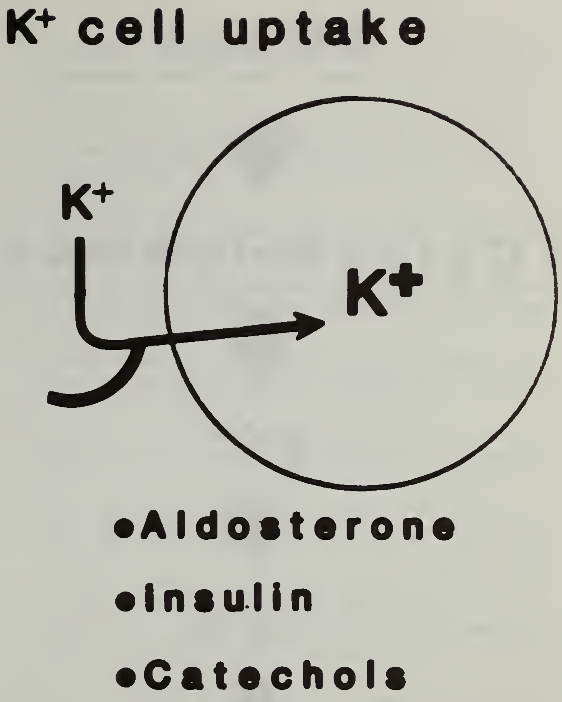

Figure 2
Control systems for K+ movement into cells. Catechols, insulin-rapid acting; aldosterone-slow acting.

Clinical Implications

The clinical implications of the phenomenon of stress hypokalemia are many and varied. These range from occurrence of hypokalemia in pregnant patients undergoing tocolytic B2 agonist therapy for premature labor to the use of B2 agonist bronchodilating therapy in patients with chronic obstructive pulmonary disease. In this latter category, it has been well documented that the use of beta agonists such as terbutaline[19, 20] and salbutamol[21] can result in acute reductions in serum potassium levels due to the B2 receptor site stimulation exposing such patients to the consequences of cardiac arrhythmias.

The major implications, however, evolve around the association of hypokalemia and the onset of ventricular arrhythmias in patients with known, suspected or unidentified cardiac disease (Figure 3). The consistent, persistent observations of Dr. Lown and his clinical group over the past decade has focused on the pivotal role of catecholamines as a triggering mechanism for the onset of ventricular arrhythmias in patients with ischemic heart disease.[22] From the original observations of an association between hypokalemia and the onset of ventricular arrhythmias due to digitalis intoxication[23] they have emphasized the linkage between the sympathetic nervous system and the genesis of cardiac arrhythmias. It is well known that catecholamines are arrhythmogenic within the environment of myocardial ischemia, especially in patients with coronary atherosclerotic disease.[24]

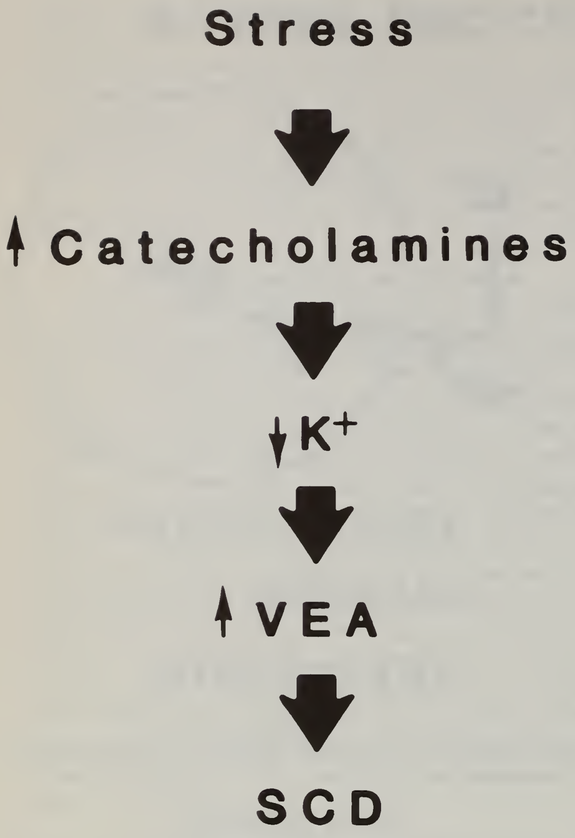

Figure 3
Proposed stress-sudden cardiac death sequence occurring via transient hypokalemia.

An important observation concerning the association between hypokalemia and the onset of ventricular fibrillation was made by Dr. M. Duke of Manchester Memorial Community Hospital in Connecticut. In 1978, he reported on a review of 1,078 patients with acute myocardial infarction who were reviewed retrospectively for an association between hypokalemia and ventricular fibrillation.[25] Of the ten patients who were receiving thiazide diuretics at the time of admission to the coronary care unit, all of whom experienced ventricular fibrillation, seven of the ten were noted to be hypokalemic with serum potassium levels 3.4 mEq/L or less. Dr. Duke emphasized that in the setting of acute myocardial infarction, especially in patients receiving thiazide diuretics, associated hypokalemia should be corrected or prevented.

In a more recent clinical investigation, Drs. Nordehaug and von der Lippe reported on a large myocardial infarction beta blocker trial conducted in Norway.[26] They noted that approximately 11% of patients admitted to CCUs as part of the trial were hypokalemic at the time of admission. The incidence of ventricular fibrillation in this patient subset was two and a half fold greater compared to normokalemic patients. The onset of complex ventricular arrhythmias in these patients was characteristically earlier than the onset of comparable arrhythmias occurring in normokalemic patients. Their report confirmed an earlier report by Drs. Cole and Solomon of the Roger Williams Hospital in Providence[27] who documented that a stepwise increase in the incidence of ventricular tachycardia and ventricular fibrillation occurs for each decrement in serum potassium levels below the lower range of normal.

Stress Categories

This newer knowledge regarding stress hypokalemia suggests that certain patients such as those with ischemic heart disease may be at risk for sudden cardiac death via the transient risk factor of stress hypokalemia.

Studies to date have emphasized the occurrence of stress hypokalemia in conditions of moderate to severe stress as occurs commonly in the intensive care units, coronary care units, post-operative patients, etc. It is clinically useful to categorize stress states based on the description of the inciting event. Such a classification would include mental stress (example: arithmetic – serial sevens), emotional stress (examples: anxiety, intense joy), physical exercise stress (example: cardiac treadmill testing), acute pain syndrome (example: angina pectoris, acute myocardial infarction), and the general category of surgical stress which would include both that related to anesthesia and that related to the surgical procedure.

Trends Concerning Choice of Beta Blocker

This new knowledge focuses attention on the B2 antagonistic properties of beta blockers. The only two categories of beta blockers available to the practicing physicians are the dominant B1 blockers, such as atenolol, and the balanced B1B2 blockers as exemplified by propranolol. There are no specific pure B2 antagonists available. Some are under investigation in research laboratories.

All of the current beta blockers used in cardiovascular medicine, for example in the treatment of patients with hypertension or ischemic heart syndromes, share a cardio-protective action due to their ability to antagonize at specific cardiac receptor cell sites the action of B1 agonists. This newer knowledge regarding stress hypokalemia points out a unique advantage of the B1B2 blockers in that the K^+ – protective mechanism against stress hypokalemia has been documented to be a B2 receptor phenomenon. Therefore, the judicious use of B1B2 blockers in such patient groups, in addition to offering the well known cardio-protection such as the decrease in cardiac deaths following myocardal infarction, can be viewed as having an additional K^+ – protective mechanism due to their B2 antagonistic component which minimizes the risk of stress hypokalemia and the potential for onset of ventricular arrhythmias.

The utility of the concept of stress hypokalemia in patients with ischemic heart disease can only be fully appreciated once the practicing physician has had the opportunity to integrate this new information into his practice of cardiovascular therapeutics.

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Scleroderma Heart Disease

C. WALLACE ANDRIAS, M.D.

ABSTRACT—It has been known for the past thirty years that the heart can be involved as a primary target organ in scleroderma. Once the heart becomes clinically involved, the prognosis is poor. To date, therapeutic interventions have been unsuccessful at reversing the pathologic process. More recently with the advent of noninvasive cardiac imaging in the area of echocardiography and nuclear cardiology, evidence of cardiac pathology has been identified prior to clinical manifestations. This article presents two patients with scleroderma with the clinical evidence of cardiac involvement and reviews the literature on scleroderma heart disease with particular attention to assessment of cardiac involvement by noninvasive techniques.

This is a brief review of scleroderma heart disease based on two cases recently seen at our hospital. Both patients had evidence of cardiac involvement. One of the problems in evaluating patients with scleroderma heart disease is in deciding if the cardiac pathology is a primary process or one secondary to other organ involvement such as lung disease with resultant cor pulmonale. In the two cases to be presented, one patient had an autopsy confirming primary scleroderma heart disease; no autopsy was permitted in the second patient.

Scleroderma is common worldwide, except in Asia. The onset of the disease is usually between the third and fourth decades of life. The disease occurs twice as frequently in females as in males. The prognosis is more serious in males, in blacks of both sexes, and in elderly individuals.[1] It has been described as far back as the 18th century with cardiac disease noted as early as 1876.[2, 3] In 1898, Sir William Osler wrote in an issue of the *Journal of Cutaneous Disease:* "in its more aggravated forms, diffuse scleroderma is one of the most terrible of human ills" and may progress until the patient is "literally a mummy." In the initial descriptions, cutaneous manifestations dominated and the visceral pathology was not recognized as part of the disease.[2] It was Matsuis' report of fibrotic visceral involvement in 1924 that established scleroderma as a systemic disease.[4] However, it was not until the monograph of Weiss, et al, published in 1943[5] that the heart was recognized as a target organ.

Pathologically, systemic sclerosis is characterized by microvascular abnormalities[6,7] along with excessive fibroblastic activity and collagen deposition in numerous organs. However, the pathogenesis of systemic sclerosis remains unknown. Evidence favors a primary vascular etiology with secondary fibrosis.[6,7,10,11] In 1976, Bernadine H. Bulkley, et al, described the myocardial lesions unique to this disease in a study of 52 autopsied patients.[12] They found a distinctive focal myocardial lesion ranging from a contraction band necrosis to replacement fibrosis throughout both ventricular walls. This finding was present in 23 of the 52 patients and in all of these patients the extramural coronary arteries were widely patent.

They also found no morphologic abnormalities in the intramyocardial coronary arteries to account for these lesions. There were no major differences in age, sex, and the frequency and severity of pulmonary, renal, or hypertensive disease to explain this myocardial necrosis and fibrosis. In the patients with cardiac abnormalities, an increased frequency of ventricular arrhythmias and conduction defects was noted. Four patients with primary myocardial disease died in intractable congestive failure. Sudden death occurred in five other patients. The authors postulated that the contraction band necrosis suggested that the myocardial damage in PSS might be due to intermittent vascular spasm of the type recognized in the digits, i.e., an intramyocardial Raynaud's phenomenon.

Case Reports

Case 1: A 47-year-old white woman first diagnosed as having scleroderma back in 1976 when she presented in congestive heart failure with atrial fibrillation, marked pedal edema, and hepatomegaly. She was treated with digitalis and diuretics with significant improvement. Following this, she was successfully cardioverted and remained in normal sinus rhythm on a regimen of propranolol, digoxin, quinidine, and furosemide. A barium esophagram done in 1976 showed diminished peristalsis com-

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C. WALLACE ANDRIAS, M.D., Chief, Cardiology Services, Lawrence and Memorial Hospitals, New London, CT; Assistant Clinical Professor, Yale University School of Medicine.

patible with scleroderma. In 1983, she again developed atrial fibrillation.

Her physical exam showed sclerodactyly, acrosclerosis, telangiectasia, loss of skin fold, blood pressure was 110/80, decreased breath sounds bilaterally with bibasilar rales. There was no murmur or friction rub auscultated. The liver was enlarged. The EKG: atrial fibrillation, right bundle branch block, old inferior wall infarction. Echocardiogram: marked right ventricular segment enlargement, segmental wall motion abnormality of the septum, mitral valve prolapse, and a small pericardial effusion. Chest x-ray: cardiomegaly with vascular congestion and interstitial edema. Clinical Course: Patient treated with diuresis and placed on Capoten and Penicillamine with some improvement; discharged home. Several weeks later, she was found dead in bed.

Case 2: A 69-year-old white male with a past history of hypertension and hypothyroidism. During the Winter of 1983, he developed Raynaud's phenomenon for the first time. Over the next several months he developed sclerodactyly and a diagnosis of scleroderma was made. He was admitted to the hospital in atrial fibrillation with a rapid ventricular response. In addition, his electrocardiogram showed signs of marked left ventricular hypertrophy. On physical exam, a Grade III/VI systolic ejection murmur was noted. Echocardiography showed a markedly dilated left ventricle which contracted poorly; left atrium dilated at 5.1cm; aortic valve consistent with aortic stenosis. Swan-Ganz catheterization: PA pressure 52/22 mm/Hg. Pulmonary capillary wedge pressure 22-25 mm/Hg. Because of the possibility of this patient having critical aortic stenosis, he was transferred to another facility for cardiac catheterization and further evaluation. However, he expired before catheterization could be carried out. Terminal event—refractory congestive heart failure.

Discussion

These two case histories demonstrate the extremely bad prognosis in progressive systemic sclerosis when there is clinical evidence of myocardial involvement. One of our patients died in intractable congestive heart failure and the other died suddenly at home. Scleroderma can take a milder form known as the CREST syndrome with calcinosis, Raynaud's phenomenon, esophageal involvement, sclerodactyly and telangiectasia. These patients do not tend to get cardiac involvement and their prognosis is much better than patients with progressive systemic sclerosis.

In 1982, Bernstein and Steigerwald, reported on the association of antinuclear and antinucleolar antibodies in PSS.[13] They found antinuclear antibodies at a titre greater than or equal to 40 in 74 of 76 patients with scleroderma. They noted nine distinct patterns. All 74 sera gave nuclear staining whereas an additional 33% had nucleolar patterns. The six nuclear patterns were centromere staining in 21 patients, fine speckled in 34, diffusely grainy in eight, homogenous in four, and coarse speckled in three. Dots were noted in six patients. The additional nucleolar patterns reported were speckled, homogenous, and clumpy. The chief clinical correlation was with anticentromere staining where a clear association with the CREST syndrome was noted in 19 of 21 patients. In addition, 19 of 27 patients with CREST syndrome (70%) also had anticentromere staining. It was noted in comparing the patients with and without anticentromere staining that the patients with anticentromere staining had twice the mean duration of disease, twice the frequency of calcinosis, and increased frequency of telangiectasia and little, diffuse scleroderma. There were fewer deaths in this group and an absence of renal disease. In our two patients, both were ANA positive with homogenous patterns and anticentromere negative.

Patients with myocardial systemic sclerosis can present in a number of different ways. They can present with EKG abnormalities before there is otherwise clinically apparent disease. On the other hand, it has been reported that the EKG can be completely normal with symptoms of severe cardiac involvement.[14] They can present with a Pericardial effusion discovered by an enlarged heart on chest x-ray and echocardiographic confirmation of pericardial effusion.[15] Often, the pericardial effusion is associated with clinical manifestations. Angina pectoris can be a feature of the disease but as shown in the study by Bulkley, the extramural and intramyocardial coronary arteries are usually patent.[12,14] Patient also can present with biventricular congestive heart failure due to myocardial fibrosis from primary scleroderma heart disease. Also, there can be a significant systemic and/or pulmonary hypertension as the sole or contributing factor in heart failure. Atrial and ventricular arrhythmias are common along with conduction abnormalities with first degree AV block being the most common.[14,16] Sudden cardiac death can also be a clinical manifestation of the myocardial necrosis and fibrosis of progressive scleroderma as shown by Bulkley and as seen in our first case presentation. Scleroderma rarely, if ever, affects the cardiac valves in a primary fashion although an apical systolic murmur has been reported as a common finding in a number of series.[14,16]

EKG/Holter Monitoring

In 1960, Orams and Stokes, reported on 49 patients felt to have scleroderma heart disease.[14] In their series, they reported the commonest finding to be abnormally low voltage. They stated the rhythm was usually sinus but both PVCs and PACs to be frequent. Also, conduction abnormalities including first degree heart block, right bundle branch block and occasionally left bundle branch block at times were noted. Also, in three of the 49 patients, there was an appearance consistent with a myocardial infarction.

In 1966, Sackner, et al, reported on 65 patients with scleroderma.[16] In their series, they found the commonest electrocardiographic abnormality to be right ventricular hypertrophy which occurred in 27% of the cases. P. pulmonale occurred in 15%. Signs of left ventricular hypertrophy were observed in 15%. Only 5% of their patients showed low voltage. Pattern consistent with acute myocardial infarction was found in two of the patients and a pattern consistent with old myocardial infarction was found in two patients. They also found first degree heart block in 15%. In a more recent study by Roberts and Cabeen in 1981, looking at 50 patients with progressive systemic sclerosis,[17] they found 32% of the patients to have abnormalities on the resting electrocardiogram. The most common were: 16% had a left anterior hemiblock, and 8% had a first degree heart block. Of note was that these authors performed 24 hour ambulatory electrocardiography and found that 62% of these patients had abnormalities. 32% had supraventricular tachyarrhythmias, 14% had conduction disturbances, and 20% had significant ventricular ectopy with 10% showing ventricular tachycardia. The authors performed intracardiac electrophysiologic studies and demonstrated functional abnormalities in the sinus node in seven patients, in the atria in nine patients, and the AV node in 10 patients. These authors postulated that the abnormalities may result from a similar pathologic process, namely fibrosis and atrophy of the proximal atrioventricular node.

In a study in 1976 by Ridolfi, et al, where they looked at the conduction system at autopsy in 35 patients,[18] 17 or 50% of these patients had myocardial fibrosis of the type seen in systemic sclerosis. However, they found sinus node fibrosis in 13 of the patients and it was as frequent in those without the myocardial lesions as those with. In this study, the atrioventriuclar node and His bundles were normal. They did find fibrotic changes in the proximal bundle systems in six patients. Their conclusion was that the high incidence of conduction disturbances found in progressive systemic sclerosis may be due to the damage to the working myocardium rather than the conduction system itself. In a study in the British Heart Journal in 1980 by Roberts and Cabeen,[19] they found the proximal portion of the atrioventricular node was consistently found to be smaller and more slender in seven necropsy studies on patients with progressive systemic sclerosis.

Summary—Arrhythmias are fairly common in progressive systemic sclerosis, both PACs and PVCs and occasionally atrial tachyarrhythmias and ventricular tachycardia are found on ambulatory holter monitoring. Holter monitoring will increase the finding of electrocardiographic abnormalities in patients with progressive systemic sclerosis from about 30% to up to about 60%. As far as conduction abnormalities, first degree heart block appears to be the most common found in 15-20% of the patients with higher degrees of heart block less common findings. Low voltage was noted in some series to be fairly common and may reflect pericardial effusion. Also, a pattern consistent myocardial infarction may be consistent with extensive fibrosis. In some series, right ventricular hypertrophy was found to be fairly common and this may be a reflection of severe pulmonary disease. In rare cases, the electrocardiogram may be completely normal in patients with documented cardiac involvement and in other cases, the electrocardiogram may be the first clinical evidence of cardiac involvement preceding any cardiac symptoms.

Echocardiography

The echocardiogram is not only a good method for detecting cardiac pathology, but is an excellent tool for serially following patients since there is no significant morbidity with this technique. The first report in the literature on the echocardiographic features of scleroderma was in January, 1977 by Eggebrecht and Kleiger where they reported on two patients with scleroderma heart disease.[20] The most thorough presentation was the study of 54 patients by Smith, et al, published in 1979[21] and a report on 24 patients by Gottdiener, et al.[22]

Pericardium—pericardial effusion was detected in one of two patients, 22 of 54 patients and five of 24 patients respectively, in these three studies. Combining the three studies, pericardial effusion was found in 35% of all the patients. In a report by McWhorter, et al, on pericardial disease and scleroderma in 1974, pericardial disease was found in 62% of 34 patients autopsied. However, 24% of those patients with pericarditis at autopsy did not have a pericardial effusion. Pericardial effusion was found in 13 of the 34 patients or 38% of those patients which correlates well with the findings on the three echocardiographic reports of the incidence of pericardial effusion. In one report, the prognosis of a small pericardial effusion was significantly better than the large pericardial effusion.

Myocardium—increased left ventricular wall thickness was reported in two of two patients in the first study, only four of 54 patients in the second article, and 13 of 24 patients in the third article. In one of the published articles, septal wall motion abnormalities and asymmetric septal hypertrophy correlated well with elevated pulmonary pressures at right heart catheterization.

Left ventricular dimension—left ventricular end diastolic dimension was found to be increased in one of two patients, two of 54 and three of 24 in the three reports. It would appear that a dilated left ventricle is an uncommon finding in scleroderma heart disease. Combining the three reports, this occurred in a total of five of the 84 patients. Right ventricular enlargement was found in 15 of 54 patients in the one report and 10 of 24 in the second report. This would appear then to be a much more common finding than left ventricular enlargement. Left atrial dilatation was found in one of two patients, seven of 54, and 12 of 24. Decreased mitral valve slope was found in 16 of 54 patients and 10 of 24 patients, consistent with decreased left ventricular compliance. Mitral valve prolapse was noted in two patients of 54, and four patients of 24. In one study, a pulmonic artery finding consistent with pulmonary hypertension was noted in four of 12 patients where the pulmonary artery could be adequately visualized.

Summary—echocardiographic abnormalities are common in scleroderma heart disease. The most common finding is that of pericardial effusion found in 35% of the cases. Also common findings are decreased diastolic slope of the mitral valve found in 33% of the patients in the three studies; right ventricular dilatation was common and found in 32% in the two reports of 54 and 24 patients, and the incidence of left atrial dilatation was 25%. Left ventricular hypertrophy shows somewhat conflicting results being common in the two smaller studies but relatively uncommon in the large study of 54 patients where it was found only concentrically in one patient with systemic hypertension and some asymmetrical hypertrophy in two patients with high RV pressures. In the report which showed increased left ventricular wall thickness relatively common, there was no electrocardiographic criteria for left ventricular hypertrophy and in this group of patients, only one patient had systemic hypertension. The reasons for this discrepency are unclear. Certainly, one would expect to find evidence of increased left ventricular mass. In the report on 34 postmortem patients, left ventricular hypertrophy was found in 47% of those patients. Right ventricular hypertrophy was found in 28% which correlates well with the echocardiographic findings in these studies.

Cardiac Nuclear Studies

There have been two reports published of nuclear cardiac evaluations of patients with systemic sclerosis. Both reports show that myocardial involvement can be detected before it is clinically apparent. In a report by Follansbee, et al, 26 patients with diffuse scleroderma were evaluated.[23] They purposely excluded patients with the CREST syndrome variant of progressive scleroderma. Also, all patients had normal renal function. No patient had physical findings of severe pulmonary hypertension or electrocardiographic findings of RVH. There were 18 women and eight men. Six patients had hypertension. Thallium exercise stress tests and exercise left ventricular and right ventricular evaluations were carried out. Of the 26 patients, 22 had interpretable exercise stress tests. Ten of these 22 had abnormal ST depressions of greater than 1 mm. No patient had ST elevation. Only one of these 10 patients had symptomatic chest pain and this patient had no ST changes. Twenty of 26 patients had an abnormal thallium scan. Eighteen had fixed thallium defects, 10 showed evidence of reversible defects. Eight with reversible defects also had fixed defects. Two of the patients only had just reversible defects. Only three had ST depression and reversible defects. Of note is that the presence or size of the defects did not correlate with the duration of disease. Nine patients had cardiac catheterization and eight of the nine had normal coronary arteries. Seven of these showed exercise reversible defects. One patient had significant disease in the right coronary artery and left circumflex and had a fixed defect on the thallium perfusion scan.

Of the 26 patients studied, left ventricular ejection fraction was abnormal in four at rest. Three had severely depressed ejection fractions. Twelve of the 26 had an abnormal response to exercise defined as less than a 5% increase in ejection fraction. Of this 12, 11 had thallium defects in addition to the abnormal exercise response: four with fixed defects, two with reversible defects, and five with both types of defects. Five of six patients with normal thallium exercise studies had also normal ejection fraction response to exercise. Seven patients developed a wall motion abnormality of the left ventricle and all had thallium defects. As opposed to the thallium studies, left ventricular dysfunction did correlate well with the length of disease. Seven of the 26 patients also had low right ventricular ejection fractions at rest and all seven had abnormal left ventricular ejection fractions to exercise. In studying the pulmonary functions of these patients, it was clear that cor pulmonale was not the principal cause of the right ventricular dysfunction. Right ventricular dysfunction appeared to be a manifestation of the same process that was occurring in the left ventricle and correlated with both left ventricular dysfunction and the size of the left ventricular thallium perfusion defects.

Summary—The authors were able to show that in these 26 patients, of whom only six were known to have any cardiac involvement prior to study, that nuclear evaluations of patients with diffuse scleroderma can detect myocardial involvement before it is clinically apparent. The authors also speculated that an abnormality of the coronary circulation may be present at the level of the intramyocardial vasculature, a suggestion compatible with the hypothesis that myocardial dysfunction in this disease is secondary to ischemic injury which eventually results in fibrosis. Whether this process is vasospastic or a structural process impeding flow in the small arteries could not be determined from this study. Also, the authors stated that there may be additional contributing pathogenic factors such as immune-mediated injury. Similar results were obtained by Alexander, èt al, who looked at 13 patients with systemic sclerosis and used nine normal controls.[24] These patients were studied with thallium scintigraphy and 2D echocardiography after cold induction of peripheral vasospasm. Only one of this group of patients had clinical heart disease and two others had atypical chest pain with poor R wave progression. No patient developed chest pain or EKG changes in response to cold pressor. The results show that of the 13 patients with systemic scleroderma, four had fixed defects consistent with fibrosis, 13 had reversible cold induced defects. Of the nine controls, there were no fixed defects and no cold induced defects. On echo analysis, 12 of the 13 developed cold induced wall motion abnormalities. Two of the 13 had fixed wall motion abnormalities. Two of nine controls also had fixed wall motion abnormalities but none of the nine controls developed a reversible echocardiographic defect.

In summary, it would appear that nuclear cardiac studies are capable of detecting myocardial involvement from diffuse systemic sclerosis before it becomes clinically apparent. Whether this information has any therapeutic implications at this time is unknown. However, since overt myocardial dysfunction in progressive systemic sclerosis is associated with such a poor prognosis, it is hoped that earlier detection of myocardial abnormalities will permit evaluation of therapies to treat or prevent this complication.

Treatment and Therapeutic Implications

At the present time, there is no effective therapy for the primary cardiac disease of scleroderma. Treatment continues to be that of standard therapy for congestive heart failure and arrhythmias. Since the prognosis of scleroderma once clinical heart disease is apparent is so poor, and since as shown in this review, there are now ways to identify the cardiac involvement prior to actual clinical manifestations, there can now be clinical trials aimed at preventing the development of fibrosis in this disease. To date, trials on D-penicillamine and corticosteroids have proven ineffective for cardiac manifestations. Again, the trials to date have been done in patients with clinically overt cardiac disease. We still await trials done on people with early evidence of cardiac involvement such as that demonstrated by nuclear methods in this paper but without any clinically overt cardiac disease. Logical drugs to try would be the calcium blocking drugs used for coronary spasm since one of the possible theories is a Raynaud's phenomenon involving small coronary vessels. Also, the renin angiotensin axis is extremely responsive to cold pressor testing in progressive systemic sclerosis.[25] Angiotensin can cause a fibrotic cardiomyopathy in animals as well as produce direct vascular injury.[26] Therefore, angiotensin-converting enzyme inhibitors such as Captopril may be of value and worth a therapeutic trial in progressive systemic sclerosis.

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Use of Colonoscopy for Localization of Bleeding Site in Severe Lower Gastrointestinal Hemorrhage

PETER A. IMMORDINO, M.D.

ABSTRACT—**Four cases of massive lower gastrointestinal hemorrhage are presented in which localization preoperatively was successfully carried out with colonoscopy. In our hands, emergency angiography was less useful. We encourage the use of emergency colonoscopies before x-ray or radioactive studies in severe lower gastrointestinal hemorrhage.**

In recent years, the high operative mortality in severe lower gastro-intestinal hemorrhage has been dramatically reversed by improved techniques of preoperative localization of bleeding site. [1-3] In the past four years, we have had opportunity to treat a total of four patients with life threatening lower gastro-intestinal bleeding requiring emergency surgery. In all these patients definitive localization of bleeding was carried out with colonoscopy. These cases are presented to demonstrate the utility of this procedure in skilled hands in the face of life threatening lower gastro-intestinal hemorrhage, and to suggest that it might be chosen more frequently as the primary diagnostic procedure prior to surgery.

Case Reports

Case 1: C.F. 69-year-old retired maintenance mechanic admitted October 19, 1980, complaining of profuse rectal bleeding of several hours duration, weakness and dizziness. He had recently been taking Anacin for his osteoarthritis. He denied any previous rectal bleeding. Past medical history included diabetes mellitus, 15 years duration. Treated with diet and orinase. He was known to be hypertensive for eleven years and was receiving Aldomet, reserpine, digoxin and low salt diet. In 1973, he suffered an acute myocardial infarction. Alcohol intake—minimal. Physical examination: blood pressure of 170/100 mmsHg; pulse, regular 124/min. Skin: warm and dry. Color: pale. Lab: WBC, 14,300 hemoglobin 14.3 gm%; hematocrit 42.4%; random blood sugar 329 mg%. Hospital course: continued rapid bright red bleeding with clots. Sigmoidoscopy revealed blood and clots above 23 cm. Colonoscopy was performed at the bedside and showed fresh blood at the descending and sigmoid colon areas. Angiography was carried out and showed no bleeding point but there was no visualization of the inferior mesenteric artery due to arteriosclerotic obliteration.

On October 20th, the patient's rapid bleeding continued and he was therefore brought to the operating room where a left colectomy and liver biopsy was carried out. Gall bladder was noted to be normal. Liver showed micronodular cirrhosis. Pathology showed diverticulosis, no definite bleeding site identified.

Over the next two months, the patient had a very stormy postoperative course, including sepsis, shock, coma, pulmonary, renal and liver failure. Additional surgery included drainage of a subphrenic abscess, colostomy for leaking anastomosis and cholecystostomy for acute cholecystitis. A brief course of hyperalimentation was terminated because of fear of further septic complications. Despite all this, GI bleeding did not recur. Patient discharged on 60th hospital day with a temporary colostomy.

He returned four months later with serum hepatitis. About a year after this he lost his left leg due to arteriosclerotic gangrene. His colostomy was finally closed in February, 1983. He continues to do well and has never suffered another colonic bleed.

Obstruction of the inferior mesenteric artery due to atherosclerosis is not uncommon. The source of distal colonic bleeding is then via the superior mesenteric artery and collateral from the marginal artery of Drummond. This is more difficult to demonstrate and frequently fails because of the distance of the injecting catheter and the interposed vascular beds absorbing the dye. Thus, the angiogram was negative for bleeding site but colonoscopy demonstrated the location with sufficient accuracy to allow a left colectomy.

Case 2: R.M. 74-year-old Caucasian male admitted 10/9 because of 3 days of bright red blood per rectum with clots and associated dizziness. Past medical history revealed hypertension and atrial fibrillation for which he was treated with digoxin and metoprolol. He was known to have Parkinson's disease and gout and was treated with allopurinol. Physical examination: blood pressure 140/80 mmsHg; pulse 80/min and regular. Rectal examination: brown stool, hemoccult positive. Admission Hct: 31.4%. Hospital course: patient underwent sigmoidoscopy with a finding of brown liquid stool above 15 cm and some small internal hemorrhoids. Nasogastric tube showed no blood in the stomach. His hematocrit dropped to 29.2% and he was given transfusion of packed red cells. On October 10, colonoscopy revealed multiple diverticulae of the sigmoid colon. There was no blood in the cecum but distal to the hepatic flexure some blood tinged material was noted with definite fresh bright red blood noted in the sigmoid colon and rectum only. Distally in the rectum, hemorrhoids were observed with no evidence of bleeding.

On the 2nd hospital day, the patient's severe lower intestinal hemorrhage recurred. At that time, he was colonoscoped to 65 cm with bright red blood noted slowly pooling at the descending sigmoid. Again hemorrhoids were not bleeding. He was started on oral kanamycin and continued on intravenous fluids and careful observation. On the 3rd hospital day, it was evident that rapid bleeding was

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PETER A. IMMORDINO, M.D., Senior Physician, Department of Surgery, Lawrence and Memorial Hospital, New London, CT.

continuing. At that point Technitium labeled red blood cell scan showed no evidence of bleeding from gastro-intestinal tract at 30 minutes. From admission through day 3, the patient received a total of 9 units of packed red cells. On day 3 following the receipt of 4 units of packed cells, his hematocrit rose only to 30.9 suggesting increased rapidity of bleeding. He underwent a left hemicolectomy with preoperative intravenous Cefoxitin prophylaxis. Pathology showed diverticulosis, diverticulitis and focal recent submucosal hemorrhage. He was discharged on the 13th postoperative day.

This case demonstrates the usefulness of repeat examinations which can be completed often in 20 minutes or less. In addition, the initial slowness of blood loss was such that: a) angiography might have been less successful in determining the site; b) we could take the time to prepare his bowel for 24 hours before surgery with immediate security of location so that we could operate any time bleeding seemed out of control. The labeled red blood cell study showed no bleeding at 30 minutes. However, we may not have given sufficient time for this study to be effective.[4]

Case 3: S.P. 74-year-old Caucasian male was admitted because of bright red rectal bleeding on day of admission. He had recently been on Feldene for osteoarthritis. He was admitted one year before for another episode of bright red rectal bleeding and at that time a barium enema showed sigmoid diverticulosis and an upper gastrointestinal series was normal. On physical examination the skin was warm and dry; blood pressure was 124/64 mmHg, pulse 82/min and regular. Hemoglobin 11.0 gms. hematocrit was 32.6%; prothrombin time was 12.8 sec; APTT 23.7. Platelets normal. Hospital course: bleeding at first seemed to stop. Sigmoidoscopy to 25 cm showed old clots coming from above. On day after admission at 8:30 P.M., patient began to suddenly pass moderate quantities of bright red blood rectally. Blood pressure dropped to 92/50. Pulse was 50 to 60 per minute and the patient appeared increasingly pale. Hematocrit 27.2%. He was given 2 unites of packed red cells. Immediate upper endoscopy was normal and showed no blood in the stomach or duodenum. Colonoscopy showed old clots in the right colon. In the descending colon the blood became suddenly more liquid and brighter in appearance. In the sigmoid there were pools of fresh bright red blood which were easily suctioned away. No definite source of this hemorrhage was noted but diverticulosis was present. Patient was given Kanamycin by mouth and given packed red cells in transfusion. On the 2nd hospital day at 11:00 P.M., he had a recurrent episode of brisk bright red bleeding from the rectum. Between the 2nd and 3rd days, he received a total of 7 unites of packed red cells in transfusion. Finally prophylactic intravenous Cefoxitin was given and a left colectomy performed. A total of 11 units of blood were given pre and postoperatively. His postoperative course was uneventful. Pathology showed diverticulosis, no bleeding site was identified. He was discharged on the 9th postoperative day.

As in case 2, we were impressed by the preoperative control with ability to re-examine the colon during different phases of bleeding and to prepare the patient for surgery. His postoperative course was quite benign.

Case 4: J.L. 51-year-old Caucasian male desk worker was admitted November 7, 1984 complaining of 48 hours of maroon to tarry stool. He had been taking 3 to 4 aspirin per day for pain relief following dental surgery. In July of 1983 he had an appendectomy for acute appendicitis. The terminal ileum was not inspected at that time.

Past medical history revealed hypertension for which he was treated with Aldomet 250 mg daily. Physical examination showed an alert, cooperative, obese white male with warm dry extermities. Blood pressure 170/80 mmsHg. Pulse 96/min, temperature 37.2. Rectal examination showed guiac 4+ stool. Hemoglobin 13.5 gms%; hematocrit, 39.5%; red blood cell count, 4.32 million. Prothrombin time was 13.1 sec (normal 10-13). APTT and platelet count normal. BUN, 27 mgs%.

The patient underwent upper endoscopy immediately upon admission revealing superficial erosions of the antrum and duodenum but no blood. At first his bleeding seemed to stop so it was decided to observe him on intravenous fluids. Some question of acute gastroenteritis with camphylobacter prompted brief use of erythromycin but neither clinical findings nor culture confirmed this. Early in the morning of the 2nd hospital day, the patient began to bleed acutely with a drop of hematocrit to 25 and blood pressure to 100-110 mms Hg systolic. Pulse rose to the same range. Transfusions of packed red cells were started. Colonoscopy revealed bright red liquid blood from ileocecal valve with only older blood in the more distal colon and neither lesions of the colon nor evidence of blood issuing from any other area.

Laparotomy was carried out immediately following colonoscopy and revealed an acutely bleeding Meckel's diverticulum which was removed with a sleeve of ileum. During the operative and perioperative period he received a total of 15 units of packed red blood cells. Postoperatively he recovered rapidly showing no sign of further hemorrhage and was discharged on the 9th postoperative day.

In this patient the bleeding site was in the ileum. The colonoscopy did not successfully visualize it. Nevertheless, it did demonstrate bright, nonclotted blood from the ileocecal valve in large quantities so that we could be quite certain that the locus was the distal ileum, and in fact made a diagnosis of Meckel's diverticulum preoperatively. This patient was endoscoped in the intensive care unit at the bedside with cardiac monitoring. The procedure lasted less than 2 hours and following this he was transferred directly to an operating table and wheeled to surgery. Blood loss during endoscopy was about 1100 cc simultaneously replaced with 2 units of packed cells and 2 units of salt poor albumin. Angiography could not have been done in the intensive care unit and transfer would have wasted precious time.

Discussion

Even in recent literature, the statement is made that colonoscopy usually cannot be performed during rapid bleeding.[5] Our experience with these and other cases has confirmed the following:

1. The expert use of colonoscopy has a learning curve that takes years rather than months to master. The technique has been used extensively in our hospital only in the past 5 years so that we are even now seeing increased skill and thus possibilities previously not considered for use.
2. In severe bleeding, colonic preparation has not been needed since blood serves as a good purge. In less severe bleeding we were free to spend 24-48 hours cleansing the colon.
3. Some obvious clues should be emphasized:
    a) The brightness and the liquidity of the blood indicates the proximity of lesion as opposed to dark or clotted material.
    b) The presence of brown stool distal to red blood implies that the lesion is proximal to the stool.
    c) Blood rarely refluxes through the ileocecal valve so that blood in the cecum but no blood in the terminal ileum usually locates the bleeding site in the colon.

The small bowel is still an area difficult to evaluate. If the esophagus, stomach, duodenum and colon are ruled out as sources in a rapid bleed, exploratory laparotomy should be carried out. If the lesion is not grossly evident on inspection, endoscopy of the small bowel can be carried out with operative manipulation of the endoscope.[6]

Finally, we must emphasize that the success of this measure depends on the immediate availability of a very skilled endoscopist.

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Acknowledgement: endoscopies on these cases were performed by Dr. John Madsen.

New Treatment for Non-Variceal Upper Gastrointestinal Bleeding

JOHN E. MADSEN JR., M.D.

ABSTRACT—The improved diagnostic capabilities obtained with fiberoptic endoscopy have not led to improved mortality for upper gastrointestinal bleeding. Finding an effective non-surgical approach to better control bleeding ulcers should decrease the need for surgery and hospital stay.

Termination of bleeding from a gastric ulcer following transendoscopic injection at the bleeding site of a dilute solution of epinephrine is reported and commented on. Among the other transendoscopic techniques used for stopping GI hemorrhage, laser therapy and electrocautery show great promise. Further studies are needed to determine which techniques are best for controlling bleeding and reducing patient mortality.

The availability of fiberoptic endoscopy for the evaluation of patients with upper gastrointestinal bleeding has lead to more accurate and quicker identification of the cause of bleeding. By identifying stomata of recent bleeding such as fresh blood in an ulcer, a clot or black slough adherent to a lesion or a protruding vessel, one can also identify ulcer patients at risk for re-bleed with its associated higher mortality.[1] The improved diagnostic capabilities obtained with fiberoptic endoscopy, however, have not been associated with reduction in hospital stay, the number of transfusions, need for surgery or mortality.[2-4] This apparent paradox may exist because bleeding stops in 80% of patients with standard treatment regardless of its etiology. Also, the greatest risk of mortality is seen in patients with associated illness and advanced age[5] and the benefit of quick and accurate diagnosis in this group may not show up in a small study of 100 patients or less.

Finding an effective, non-surgical approach to better control of upper GI bleeding should bring about improved mortality and morbidity.

The introduction of transendoscopic techniques for stopping GI hemorrhage offers much promise in this regard. Endoscopic sclerotherapy for controlling hemorrhage from esophageal varices has been shown to be effective.[6] In some centers it is the preferred treatment

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JOHN E. MADSEN, JR., M.D., Chief of Gastroenterology, Department of Medicine, Lawrence and Memorial Hospital, New London, CT.

for acute variceal hemorrhage.[6] Efforts are now being directed at finding effective ways to control bleeding peptic ulcers. The following is a report of termination of bleeding from a gastric lesion following injection of a dilute solution of epinephrine.

Case Report

An 86-year-old female felt well until the evening prior to admission when she developed nausea and hematemesis. She vomited blood three times over the next six hours and passed a tarry stool the following morning. She then became dizzy and presented at the Lawrence and Memorial Hospital emergency room.

A review of her past history revealed that three years earlier she had bled from a gastric ulcer. At that time, she was on Fiorinal and Clinoril for treatment of degenerative joint disease. She was hospitalized, received blood transfusions and responded to treatment with antacids and Cimetidine. She remained off arthritic medication and did well until several months prior to present illness at which time she was begun on Motrin. Three days prior to onset of this current bleeding episode she took six aspirin in addition to Motrin. The patient is a non-smoker and consumes three glasses of wine a day. Other past medical problems include a history of essential hypertension and recurrent depression.

Physical examination at time of admission revealed a healthy appearing woman who looked younger than her stated age. Blood pressure 120/80 mms/Hg and pulse 88. No telangiectases or other cutaneous manifestations of liver disease were noted. Lungs were clear to auscultation. No heart murmurs were noted. Adbomen was soft to deep palpation and without organomegaly or tenderness. A melanotic stool was found on examination.

Lab evaluation: Hemoglobin 12.3%. Hematocrit 37%. A nasogastric tube was passed and hemocult positive, coffee ground material returned. An IV was started and she was admitted on antacids and Tagamet therapy. Six hours following admission, she began vomiting bright red blood. Blood pressure dropped to 98 systolic. A unit of packed red blood cells was ordered and transfer to intensive care unit carried out. A gastroenterologist was consulted and, within an hour, an upper endoscopy was performed. At time of the upper endoscopy, a large amount of fresh blood with clots was noted in the fundus of the stomach. A thin stream of blood could be seen pulsating for a distance of 1.0 cm from the lesser curvature antral wall, but the nature of the underlying lesion could not be determined. At this point, epinephrine 1:1000 was diluted with 10.0 cc of normal saline. One cc of this solution was injected on either side of the spurting artery. Bleeding *immediately* stopped and, on washing, a small, fresh ulcer crater was seen. Although a dark spot in the center of this ulcer crater was felt to represent a blood vessel, no obvious protruding vessel was seen. The patient received 2 more units of blood after completion of the endoscopy. Her hemoglobin stabilized at 11.4 gms% and no additional units of blood were required. The patient was then treated with Maalox, initially on an hourly basis, and Cimetidine. No further bleeding episodes occurred and she was discharged. Six months following discharge she remained well.

Discussion

Multiple endoscopic techniques for the control of nonvariceal gastrointestinal bleeding have been reported. Since such bleeding usually stops without intervention, one cannot tell whether a new treatment modality is successful without applying it to a large number of patients, preferably in a controlled trial. Thus far, there is not enough experience with any single technique to confirm its effectiveness in controlling bleeding and in reducing the recurrence rate and mortality. The list of methods presently being investigated is interesting and long. The most promising techniques are those using heat to coagulate tissue proteins. Heat may be applied by using laser light,[8,9] electrocoagulation,[10,11] heater probe,[12] and fulgeration.[13] Topical treatment with application of tissue adhesives,[14] or clotting factors,[15] and local injection or sclerosing or pharmacological agents,[16,17] have also been tried. Magnetic tamponade, using iron powder and an electromagnet, is the most imaginative approach taken to control bleeding.[18]

Laser Therapy

The CO^2 laser is the most widely used surgical laser but since it cannot be transmitted by a quartz fiber, it cannot be used with flexible endoscopy. Both the argon and the neodynium yttrium aluminum garnet laser (Nd: YAG) are now used by endoscopists in Europe and America. The monochromatic light which laser emits is absorbed by tissue and converted to heat resulting in thermocoagulation of blood and tissue proteins (photocoagulation). The argon laser emits visible blue-green light which is absorbed by red blood cells. Unfortunately, the absorbtion of the light by blood often prevents the beam from reaching underlying tissues and blood vessels. For that reason, the argon laser is used with a jet of carbon dioxide gas to keep blood out of the field of work. The Nd:YAG is used by 95% of the hospitals in this country. It produces an invisible radiation which is not absorbed well by tissue so that it penetrates deeper than the argon laser. Because of its deeper penetration, there may be greater potential for tissue injury.[19] The endoscopic laser treatment was first used in 1975 in Germany,[20] and has now been used on over 3,000 patients.

Results from controlled trials are favorable but mixed.[8-9, 21-22] Unfortunately, a laser system is expensive, costing over $100,000. It is also costly to maintain and is not portable. Despite these limitations, it is the most successful current endoscopic technique available. In a controlled study it has been shown to decrease the incidence of further hemorrhage and the need for emergency surgery.

Electrocautery

With electrocautery, heat is generated by electrical energy and, as with laser therapy, this results in tissue coagulation. Both monopolar and bipolar probes have been used for hemostasis. Monopolar probes operate in a manner similar to present snares in which the electrode contacts the target tissue and a current passes through the subject to a ground or dispersal plate applied to the skin. With the bipolar coagulation probe, there are two electrodes separated by 1 or 2 millimeters at the end of the probe and current passes between the two poles which are in contact with tissue. Because a current does not pass through the body to generate heat, bipolar electrodes may be associated with less tissue damage.[10] As with laser therapy, a low incidence of perforation has been associated with their use.[19,23] The electrocautery unit is not as easy to use as a laser beam because direct contact with the tissue is required, unlike the laser beam which needs only to be directed at the site of bleeding.

Tissue contact with electrocautery is also associated with problems of tissue and clot adhesiveness. However, if the electrocautery can be shown to be as effective as laser therapy, it will undoubtedly, be more widely used because of its low cost and transportability which permits bedside use.

Electrofulgeration

Electrofulgeration does not involve tissue contact but, instead the electrode is placed close to the tissue and a spark jumps the gap to cause dessication. It was hoped that the lack of tissue contact would result in less damage but, in early canine studies, the opposite has been true.[13] This technique has not yet received clinical application.

Heater Probe

The heater probe is an aluminum cylinder covered with ceramic cement in which there is an electrocoil to generate heat and a thermocouple element to record temperature. The probe is designed to apply pressure to bleeding vessel so that it can be compressed while heat induces coagulation. Initial trouble was encountered controlling the depth of injury in canine gastric ulcers. This hemostatic technique has not yet had clinical trials.[12]

Thermomagnetic Tamponade

With this technique, a suspension of elemental iron powder, thrombin and a suspending solution is injected through an endoscopically passed catheter onto the bleeding lesion. An external electromagnet is then used to generate a magnetic force to tamponade bleeding. Although imaginative, this technique has thusfar not shown to be as effective as electrocoagulation or laser therapy.[18]

As with the latter three techniques, the spraying of clotting factors, the application of tissue adhesives or glues and the use of mechnical clips have not been well studied or widely used. Their application is presently limited to a few investigational centers.

Injection Therapy

Experience with injection therapy is also limited but includes reports of injection of epinephrine,[16] hypertropic saline and sclerosing agents[17] into bleeding ulcers. It is surprising that injection therapy has not been more widely reported because it is simple and most centers already have the required transendoscopic needle and solutions in their endoscopy units. Dr. P. Kortan and others have recently had success using epinephrine and saline injection, which Dr. Kortan reported on at the Spring Connecticut Regional Society for Gastrointestinal Endoscopy meeting, March 21, 1984. No complications associated with the technique have thus far been reported.

At Lawrence and Memorial Hospital, neither laser therapy nor an appropriate electrode for electrocoagulation is available. In the case report, it was felt that something needed to be done to conrol the spurting vessels seen at the time of endoscopy. Because of the technique's simplicity and apparent safety, it was elected to inject epinephrine into the tissue surrounding the bleeding lesion. A dilute solution was used to avoid tissue necrosis. It is uncertain whether the bleeding stopped in this case because of the swelling and subsequent compression caused by the injected solution or because of epinephrine induced vasoconstriction or some combination of these possibilities. Neither can one be certain that the hemostasis induced by the epinephrine injection saved the patient from surgery. As with most ulcers, and with this patient's ulcer three years ago, bleeding usually stops without any endoscopic therapy or surgical intervention. Thus far, epinephrine injection has been used in only three patients at Lawrence and Memorial Hospital, all of whom had active bleeding from the duodenum or stomach at time of endoscopy. Bleeding stopped permanently in two of these patients, including the patient above, but recurred in one patient six hours later.

Although unproven, epinephrine injection is an easy, inexpensive technique which merits further investigation. Even if the technique does not produce permanent hemostasis, the ability to temporary stop bleeding and allow clear visualization may help with other therapies such as laser therapy or electrocoagulation.[24]

Endoscopic therapy for controlling GI bleeding is already meeting with much success and shows great promise for the future. Further studies are needed to determine which if any of the above techniques is best for controlling bleeding and reducing patient morbidity and mortality. If therapeutic endoscopy does not prove to be a definitive long term treatment for bleeding from ulcers or gastritis, the ability to control bleeding at time of endoscopic diagnosis permits postponement of surgery, allowing surgery to be performed on elective rather than emergency basis.

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Automated Medical History-Taking

MORTON SOLOMON, M.D.

A patient often consults a physician for help in understanding "symptoms." The conscious mind receives and interprets information concerning the body from receptors in many organs, i.e., pain in the chest. Some sensations for some patients are not easy to describe in terms of intensity, duration, location, radiation, and factors that aggravate or relieve it. The physician must ask questions in order to classify a patient with similar patients. No matter how thoroughly the history was taken, using it for making a diagnosis must include dealing with an element of uncertainty and this "soft" data is influenced by factors not always subject to direct evaluation.

The answer to a single question is rarely sufficient to make a diagnosis. A physician may increase his confidence in his interpretation of the patient's symptoms by asking the same question several times in different ways, and noting the way a question is answered with changes in facial expression and voice. As the physician reads meaning into the patient's response, the patient is alert to the physician's reactions; thus, the personal relationship inevitably affects the data acquired, e.g., notice what happens when a physician or nurse is the patient.

It is possible that direct communication between the patient and an alternative data acquisition system, designed to ask the patient questions, store and respond to his or her answers, and provide some interpretation to the physician may save time and be more complete.

In order to make the correct diagnosis, a doctor or a machine must know the right questions to ask for a given medical problem and must ask them. The medical history collects and documents the patient's problems, *prior* visits, and previous assessments, orders, and procedures. Follow up visits begin with a review of the historical data in the previous chart. Elements of the history are usually buried in a folder chronologically organized. Usable patient problem lists remain the exception and summary extracts are usually made only

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MORTON SOLOMON, M.D., Associate Physician, Department of Medicine, Lawrence and Memorial Hospital, New London, CT.

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because of a specific need, as when a patient goes to another doctor.

The easiest alternative to a provider-obtained oral history involves the use of a questionnaire. Medical interviews are not always carried out in sufficient detail because physicians have very heavy work-loads. The development of automated medical questioning equipment which tabulates the answers to questions may be useful to both patients and physicians. Medical history questionnaires are variously classified according to who administers the questions and how. A questionnaire can be administered by the physician, an assistant, or by the patient himself, with standard long-hand notes, a preprinted form, or directly into a video terminal. The choice between a self-administered questionnaire or an interviewer is made on the basis of eductional level of the patient, his ability to read and write, and the acuteness of the illness. Generally, it is preferable to use a self-administered form and the choice is between an on-line terminal and an off-line paper questionnaire.

Questionnaires are well suited to obtaining survey information of previous immunizations, allergies, smoking and drinking habits, environmental hazards, medications, injuries, surgical procedures, family history, and the standard questions of the "review of systems." Paper questionnaires have the advantage that they are familiar, can be completed at home at the patient's convenience, and can be mailed. These forms differ in format, length, and number of branching instructions, e.g., "If you are a male, skip to the next page." The acceptance of the questionnaire is said to depend on the selection and phrasing of the questions, ease of reading, brevity, format, eye appeal and arrangement on the page to lessen reader fatigue.

Generally, patients have approved of the use of automated history-taking systems.[1] However, one study of patient reactions to the use of diagnostic computers to evaluate dyspeptic symptoms indicated that stress was more likely to have increased after the consultation if the computer had been used. Patient reactions were measured through questionnaires to assess mood and attitudes to the medical use of computers. Patients who had experience with the use of the computer had more favourable attitudes towards medical computer than inexperienced patients. It was suggested that doctors planning to use computers should take care to preserve their "human touch," particularly for nervous patients.[2] I have used a self-administered questionnaire designed by Kanner[3] to obtain complete information in my practice for over ten years.

It is inconvenient for the physician to extract the information he wants from a paper questionnaire, and either a transcriptionist or a computer can print out the positive data. Data can be entered with either a mark-sense optical reader, a keyboard, or a bar code reader. Mark-sense forms have been successful for acquiring answers to a lengthy psychological questionnaire, which is read directly by the computer and analyzed. It then generates a report before the physician even sees the patient. In general, computerized histories are more complete, accurate, and legible than those collected manually by physicians.[4]

Warner Slack was the first to establish a dialogue between the computer and the patient for collecting history data.[5] Computers have been utilized to gather medical histories for over ten years. The patient sits at a console and responds to questions displayed on the screen. The most impressive feature of this type of interview is the ability of the program to ask questions relevant to the particular patient's responses, using "branching." The computer program analyzes the patient's response to questions and determines which questions to ask next. Questions are presented to the patient on the basis of answers to preceding questions. For example, if the patient has symptoms of abdominal cramps, he or she will be questioned about diet, bowel habits, weight loss, and relation to menstrual periods. If cramps are not a problem, these questions would not be asked.

Fox and Barber suggest that a most acceptable and useful application of the techniques of computer-assisted diagnosis is in the use of "on-line symptom processing."[6] By bypassing the paper questionnaire, the clinician has access to the computer printout immediately after the computer-interview and can control the selection, acquisition, and analysis of the data collected from the patient. It is possible to ensure that the patient's replies are reliable and there is a running feedback during history-taking. A substantial improvement in diagnostic accuracy was shown without changing the traditional way clinician work.

The MICKIE system was developed at the National Physical Laboratory in Middlesex, England. The system can run on a microcomputer. The time consumed in collecting a medical history with a questionnaire or computer terminal depends more on the time it takes to read, understand the question, and decide on how to respond than on the physical act of pressing a key. This intelligent on-line history-taker could be practical if it saves time, is more accepted, and results in more accurate information. It will soon be practical to use online methods of data acquisition in the home and at the bedside. After the patient answers the questions, the doctor can view a summary of the answers or obtain a printout of the responses.[7]

Some video terminals use a light pen or a pressure-sensing screen instead of a keyboard to collect information. Devices called a "mouse" and "joystick" depend too much on hand-eye coordination to be used for patients. Fingers can also be used. If the terminal has graphic capabilities, the anatomic location of pain or some other complaint may be displayed and pointed out. A bar code reader can also be used to collect and record repetitive and routine information.

There are two possible drawbacks to using a computer. The first is information overload. The experience and intuition of the physician may lead him to pursue clues which even the most elaborate questionnaire would not get into. Physicians make their diagnostic decisions through a process of associating familiar information with *specific cues* presented *during* the examination of the patient. The clinician often has a "model" of a disease in mind, with which he compares a "snapshot" of his patient's findings. A working hypothesis of the cause of the problem is rapidly arrived at and further data is collected to support or refute the early hypothesis. If more data is presented than is useful, it becomes "noise" and the decision-making process breaks down. Similarly, if a computer presents more information than can be integrated, it will not be of any help. The application of information science to the process of clinical data gathering should be useful by helping delineate the right questions to ask. Clinicians sometimes become overloaded with irrelevant information and tend to control the inverview to keep the information down to a minimum. To handle the problem of information overload by the computer, it is necessary to define the best questions to ask and to search for the best physical signs.[8]

The second drawback is that the collection of data from a patient involves evaluating the authenticity of the data and making a decision about the credibility of the patient. The doctor must decide whether to believe that the data which he has obtained is true. When obtaining information from prisoners, disability applicants, and others, the practitioner must judge whether the patient is lying. Clinicians do this very well and machines do it very poorly. In situations where lying about symptoms is apt to occur, automated medical history taking is not apt to be useful if taken literally.

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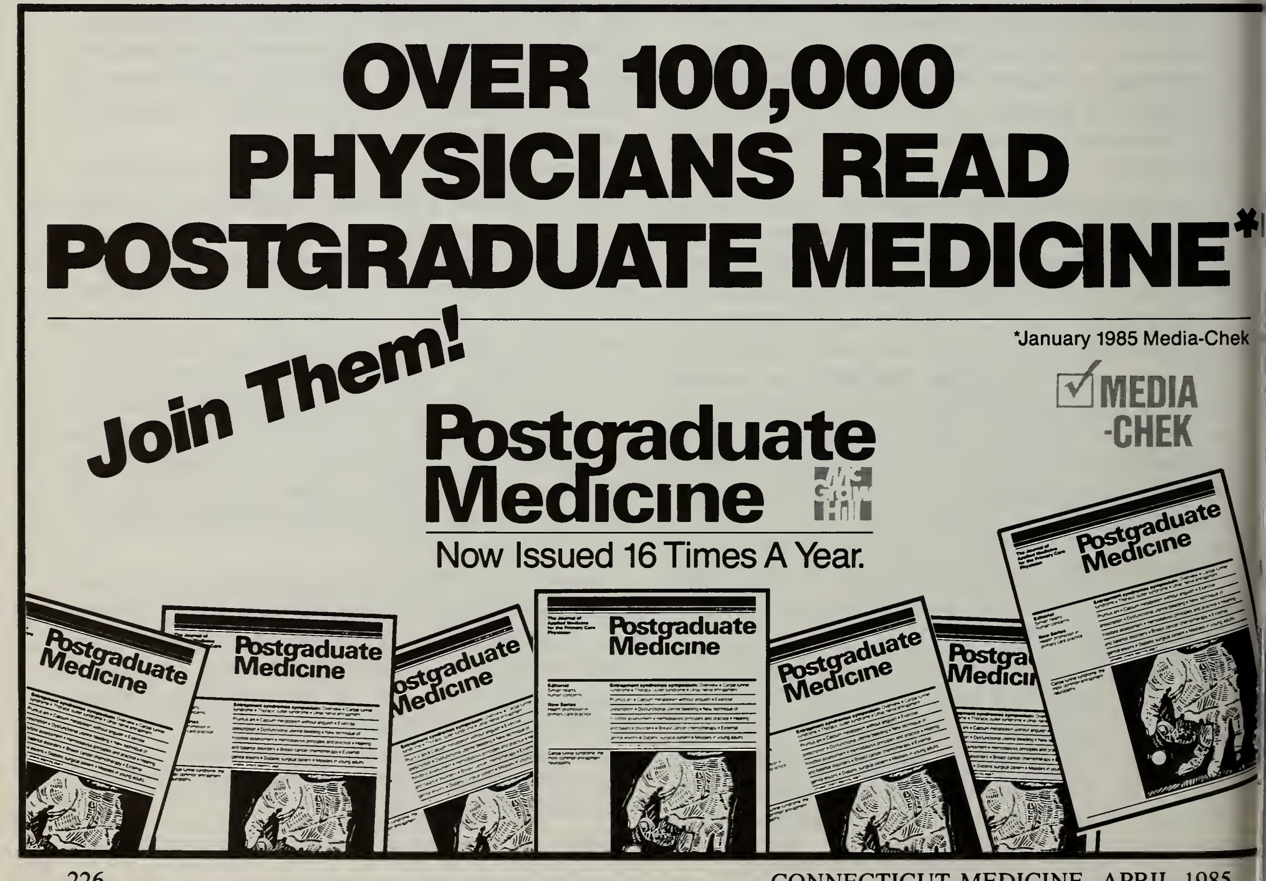

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Important Advances in Clinical Medicine

Epitomes of Progress—Plastic Surgery

The Scientific Board of the California Medical Association presents the following inventory of items of progress in plastic surgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in plastic surgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Plastic Surgery of the California Medical Association and the summaries were prepared under its direction.

Breast Reconstruction

Reconstruction of the breast following mastectomy is becoming more common as women become more aware of surgical alternatives and as newer techniques develop. Even women with significant chest wall deformities due to radical mastectomy and radiation therapy are candidates for breast reconstruction unless other systemic disease precludes an elective surgical procedure. The type of reconstruction is contingent on the degree of chest wall deformity. Each operation must be designed for the individual patient and with the objective of obtaining symmetry.

For suitable candidates, some centers are now enthusiastic about immediate breast reconstruction using an expandable submuscular prosthesis placed at the time of mastectomy and slowly inflated. Later, after appropriate skin expansion, the prosthesis is removed and replaced with a permanent implant followed by nipple-areola reconstruction. In selected cases the implant may be placed without the use of an expander.

When the pectoralis muscles have been removed and the overlying skin is tight and scarred, additional skin and muscle are needed to create the most symmetric reconstruction. The latissimus dorsi musculocutaneous flap is an excellent choice in this situation and can produce predictably reliable results when placed over a gel-filled implant. There is considerable enthusiasm regarding a lower transverse abdominal flap based on the rectus abdominis muscle, which allows for successful breast reconstruction using autogenous tissue and avoids the need for an implant. The donor site incision usually closes similarly to that of an abdominoplasty and results in a tighter and trimmer abdominal wall and a soft and symmetric reconstructed breast.

After an adequate breast mound has been created, one can reconstruct the nipple-areola complex using a variety of tissues. In the usual reconstructive procedure the pigmented skin on the medial aspect of the thigh is used for the areola, and a shared portion of the opposite nipple or earlobe is used to reconstruct the nipple.

Bryant A. Toth, M.D.
Luis O. Vasconez, M.D.

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Limb Salvage

Limb salvage, now a well-recognized technical feat, must be measured against the useful function restored and that which can be provided by a prosthesis. In the upper extremity restoration of sensate key pinch, chuck pinch and tubular grasp are the primary objectives, in that order. In the lower extremity restoration of functional gait with a sensate foot is the sole objective. Lower extremity length is of prime importance, but a useful upper extremity may be many centimeters shorter

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than a normal one. High amputations should only be replanted under the most ideal conditions in the arm and almost never in the lower extremity. Protective sensation on the sole of the foot and useful sensation on the hand will take up to two years or more to develop. It may never occur if there has been a traction injury to the proximal nerves, plexes or nerve roots. Neurotrophic ulcers or injuries to the replanted part are a constant problem during this recovery phase.

The massive amount of muscle tissue present in high amputations is extremely vulnerable to ischemia and replantation of the part may result in life-threatening complications when the circulation is reestablished. Time is of the essence in all major limb replants. Immediate arterial and venous shunts should be inserted to shorten this critical period of ischemia before bone stabilization or any soft-tissue repair.

The most common extremity salvage situation exists when there has been a severe compound comminuted lower extremity fracture with extensive soft-tissue injury. Exposed bones, joints and tendons with or without metal plates and rods must be covered by vascularized tissue. The use of proximally and distally based muscle and myocutaneous flaps often leads to further tissue loss in an already severely traumatized extremity. Wound cover can best be achieved by microvascular transplantation of muscle, with the vascular supply anastomosed to untraumatized proximal vessels. These pliable muscle structures can be wrapped around and folded into defects, obliterating dead space and bringing in needed blood supply. Ideally these transplants should be done as primary or delayed primary operations. If reconstruction is delayed for several weeks, severe problems with acute and chronic osteomyelitis are encountered. When would closure and control of infection have been achieved, then secondary vascularized bone grafts and other procedures can be undertaken. None of these operations are indicated if the nerve supply to the sole of the foot has been destroyed.

Harry J. Buncke, M.D.
Leonard Gordon, M.D.
Bernard S. Alpert, M.D.

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Craniofacial Surgery

While the comprehensive care of rare and highly complex congenital craniofacial anomalies has been left to a few centers, the application of craniofacial surgical principles and techniques has become widespread.

The classic use of autogenous iliac and costal bone grafts to repair the facial skeleton has been largely replaced by the use of cranial bone grafts. The outer table and the diploë can be safely harvested as a split graft. Aside from its use in craniofacial surgical procedures, it has been applied to correct saddle-nose deformities, erase alveolar clefts in children with cleft palate, repair orbital floor fractures and restore the contour of cranial defects. Resorption of the graft is minimal. Donor site pain and morbidity, when compared with that of the ilium and rib cage, are greatly reduced, as is the hospital stay.

In cases of severe maxillofacial trauma, the availability of computed tomographic scanning, immediate bone grafting and direct exposure and fixation of the fractures have improved the end results and lessened the need for secondary reconstruction. Difficult late residual problems such as enophthalmos can also be corrected by using craniofacial surgical approaches and techniques.

Parts of the facial skeleton are frequently electively moved to improve form and function. In conjunction with an orthodontist, difficult skeletal bite deformities can be corrected by simple procedures. Both jaws can safely be simultaneously repositioned to bring about dramatic changes.

Working as a team, plastic surgeons and neurosurgeons have augmented the time-honored stripping of craniosynostosis by repositioning the deformed bones in early infancy. The deleterious late deformity is thus lessened. In an older age group, treatment of a disfiguring craniofacial malformation has been simplified and the operating time drastically reduced, hence decreasing the morbidity and mortality of the procedure.

Thus, while the refinement in craniofacial procedures continues in selected centers, the spin-off of techniques enjoys wide application to the entire specialty of plastic surgery.

Henry K. Kawamoto, Jr., M.D.

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Recent Advances in Ear Reconstruction

Reconstruction of the ear for microtia, traumatic loss or burn sequelae has, until recently, rarely resembled the natural color and contour of a normal ear. After undergoing numerous procedures, patients were often left with noticeably deformed, scar-encased auricular facsimiles. Silicone frameworks have been disappointing as they have an unacceptably high incidence of eventual exposure, infection and extrusion.

In virgin microtia, skin coverage is usually not a problem. Brent has shown that precision sculpting of autogenous rib cartilage with exaggeration of natural prominences produces excellent contours. Proper projection can be obtained by a supportive postauricular cartilage block. A deep posterior sulcus is not reconstructed.

For posttraumatic losses or extensively scarred, failed previous surgical procedures, the temporoparietal fascia used as a vascularized flap affords the greatest opportunity for an aesthetic reconstruction. The old scar is totally resected and the carved rib cartilage is inset. The temporoparietal fascia is then raised as a pedicle flap and draped over the cartilage framework. This is covered with a thick split-thickness skin graft. Because of its filmy and highly vascularized nature, the temporoparietal fascia both conforms beautifully to the cartilaginous foundation and serves as a reliable vascularized bed for both the cartilage and the overlying skin graft.

Brent has reported an extensive experience with this procedure and notes the operation to be extremely dependable with minimal complications. Other centers have had similar favorable results.

Repair of congenital contour ear deformities without tissue shortage in midchildhood or later is a difficult surgical procedure with mixed results. Recent reports by Matsuo and co-workers from Japan have shown the efficacy of correcting auricular deformities in the neonate by nonsurgical methods. Prominent ears, cup and lop ears and other abnormal shapes are corrected by combining molding and tape splints. This must be initiated immediately postpartum and held for about four weeks for the cartilage to be permanently reshaped. The procedure requires skilled application and careful monitoring to be effective and still avoid complications such as tissue necrosis.

Randy Sherman, M.D.
Garry S. Brody, M.D.

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Suction-Assisted Lipectomy, Suction Lipectomy, Lipolysis and Lipexeresis

The terms suction lipectomy, lipolysis and lipexeresis are applied to a surgical procedure commonly known as "fat suctioning." Over the past two or three years the lay press has extolled its virtues for the treatment of "cellulite."

Historically, this technique is an offshoot of a curettement technique through a small incision. First made popular by Schruddle of Cologne, West Germany, in the early 1960s, this technique consisted of using a small incision and curetting out, through a tunnel made with a long pair of scissors, the fat of primarily the hips, knees, thighs and ankles. Dr. Schruddle currently uses a suction cannula.

The surgeon who deserves the credit for developing the suction cannula is Ulrich Kesselring of Lausanne, Switzerland. Beginning in the 1970s Dr. Kesselring used a relatively large cannula with a large aperture for carving the fat. His results have been excellent with minimal complications.

In 1977 Yves-Gerard Illouz of Paris began using a smaller type suction cannula with a high vacuum suction of about 743 mm of mercury. With this technique, large areas have been done with minimal complications such as seroma, hematoma and skin loss.

The technique is designed primarily for localized deformities such as the "riding britches syndrome," the "saddlebag deformity," bulging of the medial aspect of the knees and bulging of the abdomen, around the waistline in the flank and in the axilla and the chin. These areas have all responded well to the suction technique, the only scar being the puncture site, usually in one of the normal skin folds. The results in patients with good skin turgor and good fat density have been exceedingly gratifying.

Surprisingly, this procedure lends itself well to refinements and enhancement of normal aesthetic body contouring procedures such as abdominoplasty and thigh reduction by allowing a surgeon to minimize the extent of the dissection and length of the incision. In an abdominoplasty, deepening of the midline raphe by suction-assisted lipectomy gives a patient a more youthful appearance to the abdomen. The usual dog-ears in the traditional operation can often be eliminated without extending the incisions well over into the hip and flank area. We have also found it very useful in a facelift where suctioning the fatty tissue of the neck is accomplished and in breast reduction where there is fullness of the axilla.

Suction-assisted lipectomy has been of further benefit in many of the reconstructive operations using free flaps or transposed flaps that have irregular contour fitting. There symmetry can be improved after the wounds have healed. It has also been useful in aspirating some areas that have been injected with liquid silicone. In addition, a number of lipomas have been removed successfully using a suction cannula.

Future research with this technique may offer some help to obese and diabetic patients. Currently suction-assisted lipectomy is a useful technique in repairing local deformities and in conjunction with traditional body-contouring operations to enhance their results.

Frederick M. Grazer, M.D.

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Noninvasive Monitoring of Tissue Viability

Simple and accurate methods for predicting tissue survival will be increasingly important as reconstructive procedures reach new horizons. Work in our laboratory and others has been improving noninvasive monitoring methods.

One notable method is the use of a surface fluorometer (Fluoroscan). Blue light is transmitted to the skin surface through a flexible fiberoptic pathway. Fluorescein molecules present in the skin emit yellow-green fluorescence that is carried back through the same fiberoptic pathway and converted to a digital readout. Graham and co-workers have shown that this instrument is 500 times more sensitive than the human eye using a Wood's lamp. They have also shown that the Fluoroscan is able to predict skin-flap survival in rats. In clinical and experimental studies, we have found it simple and reliable, using less than a tenth the dose of fluorescein we had formerly used for visual assessment with a Wood's lamp. Testing may be easily repeated at frequent intervals.

Another method is transcutaneous oxygen partial pressure (Po_2) monitoring. Monitoring devices measure alterations of current in a polarographic cell induced by changes in Po_2. Most units contain a simple heating element to produce vasodilatation in the area being monitored. Thermal burns are therefore possible with prolonged monitoring at higher temperatures. Instruments that function at lower temperatures should eliminate this danger. Smith and associates have reported their experience with 65 replantations and 18 free tissue transfers. In failing replantations or free tissue transfers, changes in Po_2 appeared several hours earlier than clinical changes or temperature changes. Our own experience has been similar.

With the increasing complexity of major reconstructive surgical procedures, we feel that these and additional noninvasive tissue monitoring techniques will have increasing clinical importance and applicability.

Gerald M. Sloan, M.D.
Gordon H. Sasaki, M.D.

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Applications of Free Flaps

Microsurgical anastomosis of small vessels has become an indispensable method of transferring living tissue for reconstruction. Continuing investigation of the circulatory anatomy of skin, muscle, fascia and bone is expanding the repertoire of donor sites and treatable problems. The overall success rate of transfers of free vascularized tissue exceeds 95% when performed by experienced teams. Microsurgical training is now a part of most plastic surgery residencies, and additional training is available through active fellowship programs.

There are two areas of free flap applications: wound closure and reconstruction. Wound closure applications were discussed in the plastic surgery "Epitome" series in the June 1982 issue. As an update, free flaps are being most regularly used in closing defects due to a surgical procedure, trauma, irradiation or infection where local flaps are unsuitable, unavailable or will not heal. Heretofore-untreatable wounds can now be reliably closed in one stage. For problem wounds of the foot and the distal third of the leg, where muscle mass is sparse and cutaneous circulation is poor, closure with free flaps is now considered the treatment of choice.

Free flaps have permitted ever-increasing possibilities for reconstructive procedures. These applications include the following:

Skin. Thin flaps of skin alone can be transferred on direct cutaneous arteries to restore stability to large unstable scars. Some skin flaps (mostly from the back and extremities) have an identifiable sensory nerve that can be used to restore sensibility and are useful for reconstructing palmar and plantar defects.

Soft tissue. Serious soft tissue defects of the face due to injury, irradiation, hemifacial atrophy and craniofacial anomalies can be corrected. Flaps of muscle, omentum and de-epithelialized skin are used. For women who do not tolerate prostheses, free flaps of abdominal or buttock skin and fat have been used for breast reconstruction.

Muscle. Palsies of the face and hands, of many causes, can be reanimated by vascularized muscle transfers with motor neurorrhaphy. The gracilis and foot muscles have been the most useful.

Skeleton. Management of large skeletal defects has been improved by the realization that bone healing is superior with vascularized rather than conventional grafts. Vascularized grafts of rib, ilium, fibula, scapula and metatarsal are often the preferred treatment for many defects of the mandible, femur, tibia and upper extremity.

Viscera. Defects of viscera, such as pharynx, trachea and ureter, have been reconstructed experimentally and clinically with transfers of soft tissues or other viscera such as jejunum or appendix. Many of these have been singular cases, but the value of pharyngoesophageal reconstruction with jejunum or colon has been established.

The most important recent development is the custom design of free flaps. Isolated vessels can be transposed underneath an otherwise random flap. As healing occurs, vascular continuity is established between flap and pedicle and the entire unit can then be transferred. This has been successful experimentally and clinically.

Marc E. Gottlieb, M.D.
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Use of Nasendoscopy in the Treatment of Velopharyngeal Insufficiency

Persistent velopharyngeal insufficiency is variously described as occurring in up to 20% of any series following closure of a hard- or soft-palate cleft. Since 1876 the treatment of choice—though recently challenged by pharyngoplasty—has been creation of a pharyngeal flap. Though overall success following a pharyngeal flap operation has been relatively high, there unfortunately remains a hard core of unsuccessful cases, the reasons for which were unclear until recently. While a number of theories existed as to why the creation of a pharyngeal flap was successful, it has only recently become clear that the sole function of the flap is as an obturator. As a result, it was postulated by several workers in 1972 that the success or failure of the pharyngeal flap was directly related to the adequacy of lateral pharyngeal wall motion. Numerous studies have since confirmed this postulate and it has been clearly shown that postoperative results following a pharyngeal flap operation are based entirely on the adequacy, or lack thereof, of lateral pharyngeal wall movement.

Shprintzen in 1979, Argamaso in 1980 and Daniller and colleagues have shown that the use of preoperative planning allows for the creation of pharyngeal flaps tailormade to the size, shape and location of the velopharyngeal gap. Using a combination of videofluoroscopy and fiberoptic nasendoscopy, it is possible to tailor a wide flap where there is minimal or no lateral pharyngeal wall movement, a narrow flap for situations where there is extremely good lateral pharyngeal wall movement as commonly seen with submucous clefts.

While a combination of multiview videofluoroscopy and nasopharyngoscopy is the best way of obtaining accurate preoperative information, in an average practice it is logistically easier to obtain accurate nasendoscopy information than it is to obtain a combination of the two techniques. Use of a flexible fiberoptic nasopharyngoscope has greatly increased the ability to make accurate preoperative diagnostic judgments on the function of the velopharyngeal port and it can be done easily in an office setting.

Whereas no one flap has been found to be superior to another, it has been possible to tailor the size of flaps by reducing the amount of postoperative tubing. A flap that undergoes very little tubing will remain broad; one that is allowed to tube will basically become fairly narrow. Lack of tubing can be predicted when the superiorly based pharyngeal flap is of the sandwich variety. A superiorly based musculomucosal flap is raised in a routine manner and then sandwiched into a pocket created in the soft palate that extends from one tonsillar pillar to the other. The tubing effects on the broad, relatively short, unattached segment have been less pronounced than those observed with other varieties of superiorly based pharyngeal flaps. With the use of a 3-mm fiberoptic nasendoscope and topical anesthetic, it is possible to examine even very young children and obtain very high success rates. Thus, using careful preoperative nasendoscopy planning, it is possible to successfully treat patients with velopharyngeal incompetence, reducing persistent postoperative velopharyngeal incompetence to a minimal level. A secondary pharyngeal flap surgical procedure, while not impossible, can be extremely difficult. Reducing the chances of failure by using careful preoperative diagnostic planning has dramatically reduced the necessity for a second operation.

Avron Daniller, M.D.

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Collagen

Since 1977 when Knapp and others reported their preliminary work on the use of injectable collagen, a large number of patients have been treated in an attempt to correct a variety of textural and contour problems with various degrees of success and permanence of results.

The collagen implant, supplied as a dispersion in preloaded sterile syringes, is injected into the superficial dermis through a 27- or 30-gauge needle using a multiple-puncture technique. The material is suspended in saline and 0.3% lidocaine and is provided in two concentrations of 35 and 65 mg per ml. Studies in animals and human tissue biopsy specimens indicate that the collagen mass condenses into a cohesive implant that serves as a matrix for the ingrowth of fibroblasts and capillaries.

Before treatment, an intradermal skin test is administered on the forearm and the site is observed for four weeks to determine if any sensitivity develops. A positive skin test has been observed in 3% of recipients; they, of course, are not treated. Patients with a history of autoimmune disease or a strong allergic history should not be treated. After a negative skin test, injections are given at two- to four-week intervals, overcorrecting to 150% to 200% each time. Usually three to four sessions are required.

It is important that the texture, contour and induration of the lesion to be treated be carefully considered. Small cutaneous depressions, scars from acne, surgical procedures and trauma, depressed skin grafts and some of the changes, wrinkles and depressions due to the aging process have been treated successfully. Sharply marginated lesions such as chickenpox scars or the “icepick” scars of acne are difficult if not impossible to treat. Steroid atrophy, linear scleroderma, hemifacial atrophy and some of the residual contour abnormalities associated with cleft lip have been treated experimentally. Scars that are soft, distensible and nonstressed respond well, whereas those that are excessively firm, indurated or nondistensible do not. Occassionally, very firm areas will soften under treatment.

Problems and complications such as local tissue reaction, infection or laceration of superficial tiny blood vessel occur in less that 1% of patients. The development of sensitivity or an allergic response during the course of treatment is also less than 1%. Significant, severe or systemic complications are rare. A single case of occlusion of an intraocular vessel has occurred with a periorbital injection.

The long-term results of collagen injections to correct contour deformity vary with the type of lesion, tissue stress and unknown factors related to collagen turnover. Patients are advised that the permanence of the correction cannot be predicted and that some subsidence will occur. Supplemental injections may be required to maintain adequacy of results; however, good results without reinjection have occurred in a significant number of patients for as long as two to four years.

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Refinements in Tissue Expansion

Tissue expansion represents a physiologic phenomenon that emphasizes the principle that tissue can accommodate to a slowly enlarging mass by increasing its surface area. Development expansion of breast tissue or the cyclical enlargement of abdominal girth by a growing fetus are pertinent examples of natural tissue expansion.

“Controlled” tissue expansion was popularized by the innovative developments, begun by Dr. Chedomir Radovan in 1976, for adjacent flaps in breast reconstruction. Since then, the use of tissue expansion in reconstructive surgery has sharply widened in both clinical and research areas.

Tissue expansion is a two-staged technique initiated by placing a temporary expandable silicone implant beneath normal tissue, usually adjacent but, on occasion, distant to a defect. As the silastic balloon is enlarged by the incremental addition of sterile saline, the overlying tissue gently “expands” and is available for use after implant removal. Tissue expansion should be considered an *aesthetic* alternative in reconstructive surgical procedures, specifically in those areas where previous techniques have not provided consistent aesthetic or functional results. Because of its versatility, safety and simplicity, tissue expansion may be better tolerated in patients where more sophisticated and complicated procedures may prove to be a substantial challenge to the patient’s problem.

Advantages

- Minimal donor defect.
- Provides “like” characteristics, such as color, sensation, hair.
- Provides highly vascularized tissue—that is, delay phenomenon.
- Simple, reliable, safe and versatile.

Clinical Usage

- Head and neck reconstruction—that is, scalp, nose, external ear, mandible, congenital nevi and hemangiomas, traumatic and cosmetic defects and burn contractures.
- Breast reconstruction for Poland’s syndrome, postmastectomy.
- Trunk and perineal reconstruction for burn contracture, abdominal wall defects, pressure sores and the like.
- Extremity reconstruction for pressure sores, traumatic defects and so forth.

Preventing complications remains the key to reducing the rates of major and minor complications. These include proper patient and defect selection, refining operative techniques and improved product modification. The common complications of tissue expansion include exposure or deflation of implant and valve, infection, skin necrosis, compression of adjacent structures and hematoma or seroma.

With any innovative reconstructive procedure, a period of enthusiasm is followed by a period of reflection and refinements. The concept and practice of tissue expansion is currently in the latter period of evolution. Its ultimate role in reconstruction will be determined by increased clinical experience and the ingenuity of surgeons.

Gordon H. Sasaki, M.D.

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Biobrane—A Synthetic Skin Substitute

The development of an artificial skin to replace burn-damaged skin has been a long-held hope. Recent publications in the lay press have brought this research to the attention of the general public and have raised its expectations.

A truly artificial skin would ideally be a *permanent* substitute for a patient's own skin and, as such, should share with skin the characteristics of a protective barrier against bacterial invasion and water, protein and heat loss. The ideal artifical skin would also be flexible, sterile with a long shelf life, low in cost and readily available. In the recent past and at present, the best skin substitutes have been biologic dressings such as amnion and human cadaver allograft. These are expensive, however, must be changed frequently and are not permanent, requiring eventual replacement with autograft.

A commercially available synthetic skin substitute, Biobrane, has been widely used on burned patients as a temporary skin replacement. It has served as a low-cost alternative to human cadaver allograft. The barrier properties of Biobrane are similar to human skin; it is able to withstand bacterial wound contamination as well as fresh human cadaver allograft and is transparent, allowing visualization of the underlying wound. While still requiring eventual replacement with autograft, Biobrane serves to protect the excised burn wound from internal fluid loss and external contamination and can remain in place for many weeks. To have a knitted nylon-silicone rubber membrane coated with collagen peptides replace most of the functions of normal skin, albeit temporarily, is a definite advance over other currently available dressings.

David H. Frank, M.D.

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Burn Wound Coverage

The therapeutic imperative in the care of patients with extensive burns is wound closure. Failure to promptly restore the impaired skin barrier leads to continuing fluid and electrolyte disturbances, malnutrition and bacterial invasion. The ideal burn wound cover is, of course, autogenous skin. In extensive burns, there is a limited supply. Closure of these wounds with temporary skin substitutes allows time for reepithelialization and reharvesting of donor sites.

In the search for a substitute, several biologic and synthetic wound coverings have been used. The ideal substitute is one that adheres to the wound, allows water vapor transport, minimizes protein and heat loss, has elastic properties, is durable and flexible, maintains an intact bacterial barrier, is nonantigenic and nontoxic, antiseptic and hemostatic, is applied and removed easily, has a long shelf life and, finally, is readily available and affordable. The current available skin substitutes, none of which is ideal, include

- allografts—living donor; cadaver fresh, frozen; amnion.
- xenografts—fresh, frozen, irradiated or dried.
- tissue derivatives—collagen sheet, fabric or sponge and Bioplast fibrin.
- synthetic material—solid silicone polymer membrane, other plastics, microporous materials, adherent materials (Hydron).
- composite material—surface membrane (silicone, micropores); adherent substrate (collagen, cotton gauze, synthetic, polymer, sponge, velour, flocking or fabric).

Allografts are the closest to the ideal temporary wound cover. The limiting factors include expense, frequent changes, nonpermanence, antigenicity and availability. Recent advances in immunomanipulation, however, allow one to use allograft for prolonged periods, systematically replacing it with autogenous skin grafts. Amnion is limited by availability, pigskin by its imperfect adherence and inability to control bacterial growth and the synthetics by their poor adherence and inability to control bacterial growth. A "skin equivalent" has been developed by tissue culture techniques that, although promising, is limited by the time needed to "grow" the skin. The most promising substitute is the composite artificial skin developed by Burke and coworkers. This "skin" is a bi-layer of artificial skin composed of a temporary Silastic epidermis and a porous collagen-chondroitin six-sulfate fibrillar dermis. Following grafting, the “neodermis” serves as a template for synthesis of new connective tissue. When donor sites are ready for reharvesting, the Silastic epidermis is removed from the vascularized dermis and replaced with 0.004-in autoepidermal grafts.

Lawrence Gottlieb, M.D.
Thomas J. Krizek, M.D.

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Landmarks in Laryngology

JOHN A. KIRCHNER, M.D.

If the larynx (or "voice-box") is not the most important organ, it may well be the busiest and the most versatile. Just consider what it does during breathing, swallowing and speaking.

With every breath that we take in, the vocal cords separate enough to allow the unobstructed entrance of air; as this breath is let out, the cords approach one another just enough to provide the exact degree of resistance that the lung requires for optimal absorption of oxygen by the pulmonary capillaries; (and this is done automatically, even in the deepest sleep). During the act of swallowing, the larynx closes to prevent the entrance of food or liquids into the lung; without this reflex protection neither you nor I would be here today. And during the production of voice—a function that Evolution has added to the more important duty of airway protection—the vocal cords vibrate against one another at rates varying from 100 times per second for the basso profundo to 1000 times for the coloratura soprano. This tremendous range of pitch is made possible by instantaneous changes of tension within the vocal cords during singing, and is precisely and constantly adjusted through a series of reflex mechanisms that involve the muscles of the chest, abdomen, and pharynx among others, and, most importantly, through the monitoring mechanism provided by the sense of hearing. Surely a versatile organ!

The larynx has a long history. The Greeks had a word for it—the same one that we use today—and even for its components. The three parts of the laryngeal framework had been named by the second Century A.D.: the thyroid cartilage, named by Galen after the thyreos, the shield with a deep notch at the top for the chin, carried by the Minoan foot soldiers of ancient Crete; the hyoid, "U-shaped" bone described by Herophilus in the fourth century B.C., and the cricoid cartilage, named by Julius Pollux, after the Greek krikos, a ring carrying a seal. The space between the two vocal cords, the glottis, comes directly from the Greek word, glottis, or mouthpiece of a flute.[1]

But medical science didn't begin to get at it systematically until 1855—only 130 years ago—and then the breakthrough was made not by a physician, but by a singing teacher, Manuel Garcia. Before 1855, knowledge of the larynx was largely anatomical, gained through dissections after death, and physiological, through animal experiments. Examination of the larynx, if it was performed at all, was done by digital palpation, so that the diagnosis of a laryngeal polyp or tumor was usually made by the end of the index finger. There were those whose fingers could even diagnose vocal cord paralysis by the difference in tension in the two vocal ligaments. Many tumors, cysts and polyps were diagnosed by this method.[2] This fact is even more remarkable because topical anesthesia was not to appear before 1884. The diagnosis of cancer was usually made after death.

The year 1855 marks a revolutionary development in the diagnosis and treatment of laryngeal disease. Manuel Garcia had been born in Spain, and was living in London after fleeing France during the Revolution of 1848.

As a singing teacher, his ambition for many years had been to observe the vocal cords in action, but, like others, he considered this to be impossible. In the year 1854, while on vacation in Paris, and while walking in the garden of the royal palace, he is reported to have observed the multiple reflections of the sun on the window panes.

In his own words, ". . . suddenly I saw the two mirrors of the laryngoscope in their respective positions as if actually present before my eyes. I went straight to Charriere, the surgical instrument maker, and asking if he happened to possess a small mirror with a long handle, was informed that he had a dentists' mirror which had been one of the failures of the London exhibition of 1851. I bought it for six francs. Having obtained also a hand mirror I returned home at once very impatient to begin my experiments.

"I placed against the uvula the little mirror which I heated in warm water and carefully dried, then flashing upon its surface with the hand mirror a ray of sunlight, I saw at once, to my great joy, the glottis wide open before me and so fully exposed that I could perceive a portion of the trachea. . . ." It must be added that a fortunate combination of an insensitive pharynx and excellent

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JOHN A. KIRCHNER, M.D., Professor and Chairman Emeritus, Section of Otorhinolaryngology, Yale University School of Medicine.

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control of the pharyngeal musculature usually possessed by singers—played a significant part in the success of the experiment.[3]

On March 22, 1855, Garcia's report was presented to the Royal Society of London by Professor Sharpey, a physiologist. The report was greeted with the usual skepticism by the local medical profession, and brushed aside as a mere toy, not a diagnostic instrument. But a series of fortuitous events secured for the device a place in the practice of medicine and, for its inventor, a permanent niche in medical history as The Father of Laryngology. In 1857, a Viennese neurologist, Professor Turck, began using mirrors on long handles for examining the larynx in his clinical practice, apparently without knowledge of Garcia's work. When autumn arrived in Vienna, the sunlight which had been serving as his source of illumination began to disappear, and he put aside his mirrors. In a paper published in 1858, he stated that he was "far from having any exaggerated hopes about the employment of the laryngeal mirror in practical medicine.[4] But the instrument was saved from oblivion by a student of Turck's, Czermak of Budapest, who borrowed Turck's mirrors not for any medical purposes, but with the intention of studying the production of guttural sounds used in the Arabic language. Using artificial light which he concentrated with a larger mirror, he succeeded in getting a good view of the larynx. He also devised the concave mirror with a hole in the center for directing the light and for providing co-axial visibility.

He was not far along in his studies of guttural sounds "when," in his words, "I soon recognized, while using artificial light, the real value of the instrument I was employing." He delivered a report on the subject at a medical meeting in Vienna which was also attended by Turck.[5] Then came the usual fight about who was first, Turck claiming priority in the use of the laryngeal mirror, and Czermak granting him this priority, but pointing out, with some justification, that without his invention of the perforated concave mirror for reflecting artificial light, "laryngoscopy would have been a dead-born child."

No one would have agreed with this statement more than Garcia himself. The old singing teacher, whose students included some of the greatest singers of the 19th Century, Jenny Lind among them, was honored on his 100th birthday at a dinner given by laryngologists from all over the world. In addressing them, he commented that ". . . it is obvious that the little instrument owes the success which it has obtained absolutely and entirely to you, Gentlemen, and to the associations over which you preside. Without the powerful support of your science, it would have fallen into complete oblivion (and I as well)."[6]

Garcia died in 1906, in his 102nd year. His portrait was painted for his centennial by John Sargent. I was told by Dr. Frank Lepreau that the original hangs in the Rhode Island School of Design.

Treatment

Until Garcia's landmark discovery in 1855, the treatment of chronic laryngitis and other laryngeal disease was practically non-existent, and consisted mostly of local bleeding by leeches. Surface applications of medical agents to the larynx—a technique that became popular in the late 19th century—was considered to be impossible before Garcia's report in 1855. One striking exception to this was the 1846 report by an American, Horace Green, describing his method of applying medications to the interior of the larynx, using a long whale-bone bougie. Not only was Green's report received with complete disbelief by his colleagues, but he was severely criticized and forced to resign from his medical society, since it was generally agreed that it was impossible to introduce an instrument into the larynx.[7] Fortunately, Green lived long enough to see himself vindicated in 1863 by Dr. Louis Elsberg before the New York Academy of Medicine.

Vienna, meantime, had become the Mecca for the study of diseases of the larynx by means of the laryngeal mirror, (or "laryngoscope" as it was commonly called). Students from all parts of the world came there for instruction. New instruments were invented for applying medication to the larynx and for removing tumors. The first recorded case of removal of a tumor by indirect laryngoscopy was by Lewin, a German surgeon, in 1861.

With increasing use of the technique, laryngologists became very skillful in removing polyps and tumors from the larynx, and this seems all the more remarkable when we realize that topical- or surface-anesthesia was not available until 1884, when Karl Koller, of Vienna, demonstrated those properties of cocaine.

To remove even a loosely attached polyp by means of a laryngeal mirror and a pair of forceps requires dexterity in the physician, even with the help of topical anesthesia. But without anesthesia, the procedure requires, in addition, a completely co-operative patient. A case report by a laryngologist of the pre-cocaine era, Morrell Mackenzie, of London, illustrates the problem:

"Case 68, age 8. The child had always been humored a great deal and was, in consequence, exceedingly difficult to examine. I managed, however, at first visit to obtain a glimpse of the larynx and to see a warty growth on the right side.

"The larynx was very small and the epiglottis overhanging. Many weeks elapsed before any instrument could be introduced into the larynx and the child had to undergo a very laborious training. On each occasion ice had to be sucked for some time even before a laryngeal mirror could be tolerated. He was nearly six months under treatment and during that time attempts at removal, often unsuccessful, were made almost daily. Ultimately the whole growth was removed."[8]

I think you will agree that this was a remarkable accomplishment. And it was only one of many. Mackenzie's report of 100 laryngeal tumors removed by indirect laryngoscopy appeared 13 years before cocaine anesthesia was introduced into medical practice.

But despite this technical skill, the general laryngologist may have caused as much disease as he cured before the principles of Pasteur were applied to medical practice.

In those days of rampant tuberculosis and syphilis among those with chronic ulcerative laryngitis, the laryngologist was using the camel's hair brush to apply medications to the larynx and pharynx, using the same brush in patient after patient, often with little care in cleaning it. The same was true of the tongue depressor. One writer later commented:

"That communicable diseases were not more often passed from one patient to another can only be explained by the germicidal qualities of the silver nitrate, iodine and other chemicals that were being used."[2] (Hippocrates once cautioned that "where a doctor cannot do good, he must be kept from doing harm.")

With the arrival of cocaine anesthesia in 1884, it was inevitable that a more direct method of examining and treating the interior of the larynx would develop. In 1895, Kirstein introduced a technique which he called autoscopy. The instrument was a flat metal blade, very much like that used by today's anesthesiologist for intubation, but with a primitive system of illumination.[9] Further improvements by Brunnings, Mosher, Chevalier Jackson and Paul Holinger laid the foundations for modern endoscopic examination.

Surgery

As so often happens, necessity was the mother of invention. In 1778, a Frenchman got a piece of meat stuck between his vocal cords. A surgeon named Pelletan used a median thyrotomy to remove the meat.[10] (The Heimlich maneuver was not yet available.)

Thyrotomy, or laryngofissure, consists of opening the larynx by making a vertical cut in the front of the thyroid cartilage. This operation was occasionally used in the latter 18th and early 19th century for removing benign polyps from the larynx. It was first used for laryngeal cancer in 1851 by Gurdon Buck of New York. His preoperative diagnosis, however, was benign laryngeal polyps, but surgical exposure revealed obvious cancer, too far advanced to be removed.

Dr. Buck had, nevertheless, achieved his place in medical history as the first to operate on laryngeal cancer. But he was not among those who "have greatness thrust upon them," because he had already (in 1848) collected 49 cases of laryngeal growths and had removed several large tumors, operating by the sense of touch.[11] And we must be fair: the pre-Garcia surgeon was working under handicaps that we would consider absolutely prohibitive. It would be another 18 years before Thomas Edison would provide him with adequate illumination; ether anesthesia was known, but was not in general use for laryngeal surgery. There were no specific tests for the three diseases that most often produced chronic ulcerative laryngitis: tuberculosis, syphilis, and cancer.

The first long-term cure of cancer by laryngofissure was achieved in 1867 by an American, Jacob da Silva Solis-Cohen of Philadelphia, whose patient lived for 20 more years and eventually died of apoplexy. But this case was one of the rare successes with laryngofissure.

The operation gradually acquired a bad reputation because the operative mortality was unacceptably high, and the cure rates almost non-existent. Of the 20 patients operated upon by laryngofissure by the year 1878, only one remained free of recurrence. Nearly all the others were dead within one year. At the turn of the century, surgical success was measured more by the percentage of patients surviving the operation than by the cure of cancer.

Felix Semon, the leading laryngologist of England in 1894 reported, with obvious satisfaction, that there had been only two operative deaths among the eight laryngofissures he had performed. We could hardly share his enthusiasm today. Operative mortality for partial laryngectomy approaches zero.

The drop in mortality rates toward the end of the 19th century resulted from improvements in anesthesia, surgical technique and postoperative care. Laryngofissure in the early 19th century was performed with no anesthesia whatever. The surgeon had to be fast, and probably very persuasive.

When one reads descriptions of some of the laryngeal operations even after local anesthesia was introduced, it becomes obvious that the term "patient" was well chosen. He was awake during the procedure, usually struggling from pain and coughing up blood in an effort to breathe. The surgeon, meantime, had no electrocautery to control bleeding, no mechanical suction to keep blood out of the trachea, no endotracheal tube to insure tranquil anesthesia and no electrically powered headlight. Imagine a surgeon being asked to work under these conditions today. The resulting outburst would be the subject of conversation in the nurses' locker room for months.

As technological advances were adapted to surgical practice, mortality rates dropped, so that by 1919 St. Clair Thomson reported 38 laryngofissures without a death. Cure rates for laryngeal cancer gradually improved, and in 1927 Chevalier Jackson reported 82% of his laryngofissure patients as showing no further evidence of cancer.

With such spectacular results, why has laryngofissure virtually disappeared from our operating room schedules? It has disappeared because of two developments in this century, (1) radiation therapy and (2) laser beam surgery.

Before 1919 only occasional attempts were made to treat laryngeal cancer with radium or with external irradiation, and the results were usually disastrous: loss of overlying skin, massive edema and airway obstruction, and necrosis of the thyroid and cricoid cartilages. Worse yet, the radiotherapist was deprived of even a Pyrrhic victory: the cancer usually emerged from treatment battered but unbeaten.

In 1919, Coutard, a physician at the Curie Foundation in Paris treated a patient with laryngeal cancer, and with good results, using a new technique which he had devised. His method was to deliver small fractions of the total dose in daily treatments over a long period of time. He determined the daily dose by observing the degree of erythema developing in the skin of the neck during the course of treatment. He continued to use this form of radiotherapy, and by 1926 he had treated 77 patients with cancer of the larynx. Of these, 22 survived 5 years or more.

Although this cure rate of 30% was better than others were obtaining at that time, it is low by today's standards, and complications were frequent, particularly second and third degree burns of the overlying skin.

The problem that plagued the radiotherapist in the first half of this century was that much of the ionizing radiation intended for the cancer was being absorbed by the patient's skin. What was needed was a machine that could drive the radiation deep into the tissues before ionization occurred, so that the skin would be spared.

In 1948, Dr. Gilbert Fletcher, head of the Department of Radiotherapy at the M.D. Anderson Hospital in Houston, proposed to his colleagues in Physics and Atomic Energy that a machine be developed that would operate at much higher voltages than the 250,000 volt unit then in common use. The result of their work was the cobalt-60 unit which became a working reality in 1954, and which served as the prototype of more powerful and more highly refined devices that later developed. Using such equipment, the radiotherapist today can cure 85 to 90% of early vocal cord cancers and with restoration of normal voice in most cases.[12]

But radiotherapy is not without its problems: treatment usually requires daily visits for 5 or 6 weeks, and this is not possible in many parts of the world. A second, radiation-induced cancer may occur in as many as 8% of patients so treated.[13] Necrosis of the thyroid or cricoid cartilage occurs in 1 to 2% of patients treated by full-course radiotherapy.[14] A troublesome dry mouth and throat, with loss of taste often occur when a large area of the neck has to be included in the treatment field. For these and other reasons, surgeons continued to search for simpler and, perhaps, less invasive methods of eliminating cancer, and at one procedure if possible.

For the answer to this problem we must move into more recent history. The breakthrough came with the adaptation of the CO2 laser to the surgical microscope by Gezo Jako and Stuart Strong of Boston University in 1972.[15] This technique brought surgery of the vocal cord to a level of exquisite precision. The laser beam, directed through the surgical microscope, allows an incredible degree of control in resecting small lesions on the vocal cord, with minimal reaction and virtually no bleeding. The procedure can be performed entirely through the laryngoscope and, except for the general anesthesia that is required, the patient could be sent home the same day. An unavoidable injury to the vocal ligament immediately underlying the tumor usually results in some degree of dysphonia, but this is minimal, and usually no worse than the hoarseness that occasioned the patient's initial visit to his doctor.

Hemilaryngectomy

The malignant growth that is too large to remove by laser surgery is usually unsuitable for radiation therapy, but may still be suitable for the so-called hemilaryngectomy, which removes half the larynx but leaves the patient with a functioning voice.

The first genuine hemilaryngectomy was performed by Billroth in Germany on July 7, 1878, but it was followed by a recurrence after six months. Although the operation was later modified and improved by Themistocles Gluck, it required a temporary fistula and carried a significant morbidity including aspiration. In 1929 a French surgeon, Hautant, solved the problem of the postoperative fistula with his technique of primary closure of the surgical defect, but his operation still carried a high rate of recurrence.

In the 1940's, the operation's limitations began to be recognized, and more radical surgery employed for lesions that had previously been considered suitable candidates for partial laryngeal resection. Characteristic patterns of growth and spread of cancer within the larynx began to be understood on the basis of LeRoux-Robert's 1936 report of full-size sections of surgical specimens that had been removed by total laryngectomy. In more recent years, celloidin-mounted surgical specimens have provided more precise documentation of cancer's itinerary through the larynx and demonstrated the areas where cancer is most likely to have escaped the surgeon's notice, and to have been cut across at the operation. The technique is slow, laborious and expensive, so that such studies are being conducted at probably not more than three institutions in North America, including the one at Yale.

Supraglottic Cancer

Cancer of the supraglottic larynx—the epiglottis and false vocal cords—provides us with an excellent example of how a part of the larynx invaded by cancer can be removed while, at the same operation, the true cords are preserved and the functions of voice and airway protection are maintained.

A feature that is probably unique to the larynx is its division into anatomic spaces bounded by elastic and connective tissue membranes. In 1891 an Austrian anatomist, Hajek, injected saline into various parts of the cadaver larynx and demonstrated a sharp boundary along the lower edge of the ventricular band, below which saline did not spread. Even with the most extreme degrees of supraglottic swelling, the true vocal cords were not involved in any way.[16] This observation has been verified since that time by others who used dyes or radioactive isotopes.

On the basis of these observations, a South American laryngologist, Prof. Justo M. Alonso, of Uruguay, made medical history in 1944 when he reported cures of supraglottic cancer by a technique that removed only that part of the larynx above the vocal cords, the "horizontal supraglottic partial laryngectomy." In reporting his technique, he condemned what he called the "dogmatic rigidity" of the standard surgical procedures then in use, and recommended that the surgeon respect this intralaryngeal boundary that was put there, as he said, "by a hand much wiser than ours" and which allows safe removal of the tumor while sparing the patient's voice.[17]

Subsequent modification in the technique during the 1950's by Ogura of St. Louis, Max Som of New York and Ettore Bocca of Milan approach the objective aspired to in all cancer operations: high cure rate with maximum preservation of function.

As we look forward, are there any landmarks taking shape on the horizon? When I consider what has developed in this field in the 30-plus years since I gave my first lecture to a History of Surgery audience soon after arriving in New Haven in the early 1950's, it would have required a crystal ball to conjure up such developments as the flexible fiberoptic laryngoscope that not only simplifies examination and biopsy but allows the patient to observe on the video screen the appearance of his own larynx during the examination. The CT scan and the nuclear magnetic resonance device would have seemed like science fiction. Who could have suspected that the surgical microscope, being developed by the Zeiss laboratories in Germany, would revolutionize the practice of ear surgery? And the idea of directing a laser beam through the lens of the microscope for surgery of the vocal cord would have been like a pre-view of Star Wars. So much has developed in the very recent past that it is difficult to imagine any landmarks on the Laryngological horizon. But let us remember that in 1899—86 years ago—the Director of the U.S. Patent Office urged President McKinley to abolish the office, since, as he wrote, "Everything that can be invented has been invented."

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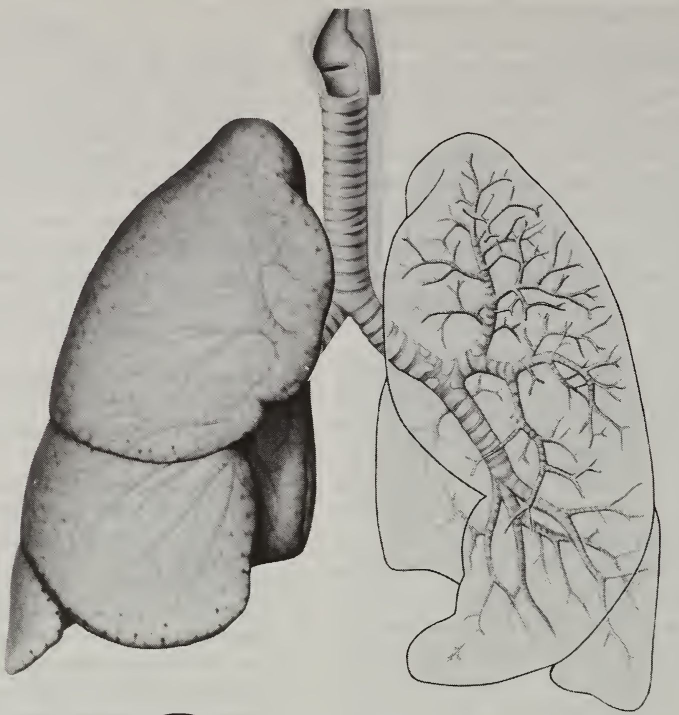

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Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out.

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Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[0617B2R]

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Percutaneous Transluminal Angioplasty (PTA)

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Because the technique of percutaneous transluminal angioplasty (PTA) has therapeutic potential and is one of increasing interest to physicians,[1-3] AMA's Council on Scientific Affairs in December 1981, established a panel* to review medical knowledge about this new technique and experience with it to date. The CSA requested that the panel report on the therapeutic use of PTA in the iliofemoral, coronary and renal artery beds. The panel's report follows.

PTA—The Procedure

The main principle of percutaneous transluminal angioplasty (PTA) is the same, whether the procedure is used in the iliofemoral, renal or coronary artery bed.[2] A double lumen dilation catheter, with a strong, non-elastic balloon made of polyvinyl chloride or polyethylene annealed to the tip, is introduced into a mainstream vessel, either directly through the skin or by cutdown. Then the catheter is guided to the site of the lesion and positioned so that the balloon segment lies within the area of vascular stenosis. A 'guiding' catheter is used to direct the balloon catheter to the lesion if the target vessel is part of the coronary artery system. It is also used in some situations involving the renal arterial system. PTA should be limited to one vascular bed per procedure.

Inflation of the balloon with a solution of normal saline and contrast medium, to 5-15 atmospheres' pressure, produces splitting and/or compression of the intimal and medial portions of the diseased artery.[4] While the amount of splitting and compression may vary from one patient to another, the major component in most atheromatous lesions probably is longitudinal splitting. The overall result of balloon dilation is an increase in lumen size and an increased blood flow through the previously stenotic vascular segment. Objective measurements of blood pressure gradients across the stenotic segment can be obtained before and after the procedure. If the PTA is successful, the pressure gradient across the stenosis is eliminated or markedly reduced.

Careful patient selection, experience in manipulating catheters, and meticulous technique are important contributors to the success of PTA procedures. The operator's experience in the angiography of the specific vascular bed where the PTA is to be performed is crucial. Also, physicians who attempt PTA in any vascular bed must work in a setting where they are able to deal promptly and efficiently with possible complications. Specifically, the support of vascular and cardiac surgical teams is essential. A learning curve is associated with PTA: at any center there should be demonstrated improvement in the success rate with increasing experience.[3]

There are various protocols for the use of pharmacologic agents before, during and after PTA, that may include treatment with anti-platelet agents such as aspirin, persantin or sulfinpyrazone, with vasodilating agents such as papaverine, calcium entry blockers and nitrates, and with low molecular weight dextran and anticoagulants. None of these agents has been shown convincingly to change the primary success rate or the rate of subsequent re-stenosis. The panel recommends the use of heparin and nitrates during coronary artery PTA, and the subsequent administration of an antiplatelet agent.

If re-stenosis of an artery occurs, a second PTA procedure may be performed. Because PTA and surgery can provide only symptomatic relief and do not affect basic pathologic processes, it is important for the patient to participate in his or her therapy by taking actions that may diminish the risk factors for atherosclerosis, such as eliminating the use of tobacco, reducing weight, increasing physical activity, and controlling hypertension and hyperlipidemia.

PTA and the Iliofemoral Arteries

The role of PTA in the treatment of peripheral arterial disease is still being defined. Problems with studying

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This report is not intended to serve as a standard of medical care: standards of medical care which are determined locally and are constantly subject to change are established on the basis of all the several factors of the individual case.

*Panel members include: John E. Albers, M.D.; John J. Bergan, M.D.; Peter C. Block, M.D.; Ray W. Gifford, M.D.; Clarence E. Grim, M.D.; Andreas Gruentzig, M.D.; Melvin P. Judkins, M.D.; Theodore C. Doege, M.D., Secretary.

that role relate to patient selection and to differences in the lesions involved. Comparing the results of different studies is difficult, because not every reporting group uses standard methods of describing immediate outcomes and long-term results.[5-9] For instance, procedures for evaluating the results of PTA have included the use of Doppler techniques to measure arterial pressure, pulse volume recordings, direct measurements from angiographic films, and unspecified "clinical procedures."

The panel believes that the indications for using PTA in the palliation of arterial occlusive disease are similar to those for performing surgical bypass grafting,[5,6] namely, the failure of conservative measures, and the progression of symptoms or signs of severe ischemia or limiting claudication caused by single or multiple stenoses of the iliac and femoral arteries. The symptoms and signs may include foot and toe pain at rest, ischemic ulcers, and minor gangrene.[8] While current preference is to treat localized stenoses, occlusions of the superficial femoral artery less than 10 cm long, and of the iliac arteries less than 2 cm long also may be treated. There are examples of successfully treated occlusions and stenoses up to 36 cm long,[10] but the beneficial results of such treatments may be short-lived. PTA is especially worth considering in a patient for whom surgery would entail a high risk, such as one with cardiopulmonary insufficiency or with extreme obesity.

Contraindications to PTA are the absence in the patient of a satisfactory entry site for the catheter or the presence of acute embolism or thrombosis.[9] An example of an unsatisfactory entry site is an area with an infection or one near which there is an arterial aneurysm.

Reporting the results of PTA should include the proportion of procedures resulting in immediate success, the proportion achieving long-term patency as defined by hemodynamic measurements, and the rate of complications associated with the procedures.

For dilation of iliac artery *stenoses,* immediate success rates range from 79% to 93%, and 70% to 80% of the treated vessels may be patent after two to three years (Table 1). In the study of Spence et al,[8] there was immediate success in 84% of treatments of femoral artery stenoses, and 70% of the vessels were patent after three years. Gruentzig's group treated 600 persons with stenoses of the femoral and iliac arteries.[2] In the treatment of iliac stenoses, their primary success rate was 92%, and the patency rate after two years was 83%. In the treatment of femoral artery stenoses, the primary success rate was 84%, and the patency rate after two years was 75%.

The study of Martin et al[11] is informative about the treatment of arterial *occlusions* with PTA. The study compared PTA and saphenous vein bypass grafts in patients treated during the same three-year period at the same institution. It is recognized that the lesions selected for treatment with the two modalities were not necessarily the same. The proportion of arteries initially patent after PTA procedures was similar to that of arteries patent after reconstruction with saphenous vein grafts. Two years after the procedures, 57% of the arteries in the PTA group remained patent, and 56% of the saphenous vein grafts remained patent.

Zeitler et al[7] described the results of 437 procedures involving femoral artery occlusions. There was a "good initial result" in 73% of the procedures (Table 1). In a group of 79 patients tested later, 60% of the vessels remained open after two years, and 20% of the vessels were patent after 6½ years.

In Zeitler's cooperative study of 1,401 patients,[7] major complications included thrombotic occlusions (64 patients, 5%), emboli (47 patients, 3%), and hemorrhage (37 patients, 3%). In Martin's study of 46 patients who had PTA for femoral artery stenosis, 5 (11%) had large hematomas; of the 5, two required transfusions and one required further surgery.[11] Spence et al[8] listed 13 definite complications among 239 persons who had PTA of the iliac and femoral arteries, a rate of 5%. These included death from hypotension and stroke in one patient, stenosis converted to occlusion in 6 patients, transient renal failure due to contrast medium overload in three patients, and embolization, perforation and bacterial endocarditis, each in one patient.

Overall, the rate of nonfatal complications associated with PTA of the femoral and iliac vessels is believed to be about 5%,[8] and this rate may be compared with that of significant complications associated with surgical reconstruction, which is believed to be 1%-2%.[5] Spence, et al state the mortality associated with femoral and iliac PTA is about 0.4%, which is less than the average mortality rate of 4% that they ascribe to femoropopliteal surgery and the mortality rate of 1%

Table 1
RESULTS OF PTA OF FEMORAL AND ILIAC ARTERIES

Author (ref. no)	*No. Procedures Treating Stenosis*	*Occlusion*	*Primary Success (%)*	*% Patent After 1 yr.*	*2 yr.*	*3 yr.*	*Nonfatal Complications*
Femoral arteries							
Martin (11)		46	76	57	57		11
Zeitler (7)		437	73*		60		15
Spence (8)	122		84	80	75	70	not stated
Iliac arteries							
Zeitler (7)	262		79*			69	6
Spence (8)	160		93	93	82	79	not stated

*Defined as "good initial result"

that is described by Abbott.

In evaluating the risks and benefits of PTA, one must consider not only the relatively low morbidity and mortality that are associated with the procedure, but also the fact that PTA may be done under local anesthesia, requires fewer days for hospitalization and fewer weeks for complete recovery,[7] may be less painful than surgery and, in the instance of PTA involving the iliac arteries, avoids the risk of severing autonomic nerves.[9] PTA may be repeated if there is recurrent stenosis, and it may be followed by a surgical procedure,[6] or vice versa.

PTA and the Coronary Arteries

Although there is variation among institutions, on the average about 50% of all patients undergoing coronary artery catheterization studies are candidates for coronary artery bypass graft (CABG) surgery;[12] of the 50%, about 10% of the patients may be candidates for percutaneous transluminal angioplasty (PTA) with current techniques. While the following guidelines may be used in selecting patients for PTA, individual circumstances also may be important in deciding for or against the procedure.

Minimal indications for PTA of the coronary arteries are angina, and objective evidence of myocardial ischemia, and a lesion technically amenable to the procedure. Relatively asymptomatic patients with strong objective evidence of myocardial ischemia, or symptomatic patients controlled with medical management but having limitation of physical activities beyond their desires, may also be considered for PTA. Any candidate for coronary artery PTA also must be a candidate for coronary artery bypass surgery and be willing to accept such surgery, if a complication of PTA occurs.

The ideal candidate for PTA has a short history of disabling angina, and single vessel disease with a proximal concentric lesion. The ideal lesion is non-calcified and not longer than 1½ cm. PTA may also be used in those patients whose co-existing conditions make CABG surgery unusually hazardous. While PTA may be considered in patients who have significant obstruction in one major coronary vessel and minor involvement of other coronary vessels, use of the procedure if there is more extensive disease remains investigational.

A patient who has re-developed stenosis at the site of a prior obstruction may have PTA again. The basis for the decision to repeat the procedure is the length of time between the successful dilation and the recurrence of stenosis: the longer the interval before re-stenosis, the better is the chance of success with repeat PTA. Experience has shown that if re-stenosis occurs within three months after a second successful PTA procedure, treatment with bypass graft surgery is preferable. Dilation of isolated stenoses in bypass grafts has been successful in some patients, but the long-term success rate with dilation of grafts is not as good as with PTA of the patient's own vessels.

Because of complications that may occur with PTA, consultation with a cardiovascular surgeon is mandatory before the procedure; and, during the procedure itself, there must be surgical back-up.

Coronary artery PTA should be applied only selectively in patients with left main coronary artery stenosis, because of their substantial risk of death following the procedure.[13] Increased risk also can be expected in a patient with multiple stenoses in the same vessel or with markedly calcified lesions. If there is a stenosis at the bifurcation of a major vessel, PTA could occlude a major branch, and the procedure is contraindicated. PTA in patients with double or triple vessel involvement, or with total obstruction of a coronary vessel is investigational.

While the National Heart, Lung and Blood Institute recently reported an overall success rate of 59% to 63% in 1,500 patients from 73 participating centers using PTA[1, 14] other reports indicate that the rate of successful dilation with PTA may approach 90%.[3] Improvements in symptoms, as judged by increases in exercise tolerance and working capacity, have occurred in 80% to 85% of the patients whose coronary artery stenoses were diminished by more than 20% as judged by angiography. Long term results are not yet available.

A patient with stenosis of the left anterior descending coronary artery is more likely to have a good result after PTA than a patient with a lesion of the right or of the circumflex coronary artery. A poor result from PTA may be due to an inability to traverse the lesion or to dilate it.

The overall mortality rate following PTA is about 1%,[13] but the rate is somewhat higher in patients who have had previous CABG surgery, perhaps due to the increased risk of complications from repeat surgery if the PTA is unsuccessful. In 6% to 8% of the patients who undergo coronary artery PTA, there is sudden occlusion or marked decrease in blood flow at the site of the attempted PTA, with persisting pain and impending myocardial infarction. This makes necessary emergency coronary artery bypass graft surgery. About half of these patients will have electrocardiographic or enzymatic evidence of myocardial infarction. Some patients without symptoms have angiographic evidence of intimal dissection of arterial walls that necessitates emergency CABG surgery.

Sudden occlusion of a coronary vessel associated with PTA may be caused by arterial spasm that can be relieved by the use of calcium entry blockers or intracoronary nitroglycerine. The rates of other complications inherent in PTA appear to be similar to those associated with cardiac catheterization and coronary angiography.

The use of intracoronary artery streptokinase in the treatment of the complications of PTA is considered to be an investigational procedure.

Results of coronary artery bypass grafting and of PTA are similar in comparable groups of patients. In patients undergoing CABG surgery for single vessel disease, the mortality rate ideally is under 1%,[15] and the perioperative myocardial infarction rate should not exceed 5%. Graft patency should be 75% after 5 years.[16] Morbidity related to surgery is, of course, more serious than with PTA, and there are more possible complications. Successful PTA can be less costly than surgery because of shorter hospital stays and fewer complications.

Mortality associated with CABG surgery is greater in those patients who require surgery because of complications related to PTA. This is due in part to the emergency circumstances of the operation and also to the increased probability of myocardial infarction at the time of PTA or shortly thereafter. The mortality associated with surgery under these conditions can be 3 to 4 times greater than with elective surgery.

PTA and the Renal Arteries

Renal artery stenosis can be responsible for hypertension and decreased renal function, or it can occur without detectable change in blood pressure or renal function.[17-19] In the majority of cases, the stenosis is caused by atherosclerosis or fibrous dysplasia of one or more layers of the arterial wall.

At present, renal artery PTA is indicated only if a stenotic lesion is responsible for hypertension or impaired renal function. If a stenotic lesion is present, then the treating physician must determine whether or not it has functional significance. The most reliable predictor that correction of the stenosis will cure or improve the hypertension is plasma renin activity in the venous blood draining the kidney supplied by the stenotic renal artery, that is at least one and one-half times higher than the renin activity in the venous blood draining the contralateral kidney.[19]

Because PTA of a renal artery stenosis has the potential for serious complications, the panel believes that PTA to improve hypertension should be attempted only if renal vein renin assay results are abnormal or the hypertension cannot be controlled medically. However, the findings of hypertension, renal artery stenosis, and an abnormal renal vein renin ratio do not necessarily mandate treatment of the stenosis by either PTA or surgery. Indeed, if the patient's blood pressure can be adequately controlled by medical means without bothersome side effects, and renal function does not deteriorate, then there may be little to gain by attempted PTA or surgical repair.[18]

Good blood pressure control does not necessarily prevent progression of a renal artery stenosis; therefore, serial measurements of renal function should be obtained in all patients who are being managed by medical therapy. If the blood pressure cannot be kept at a diastolic level of less than 90 mm Hg, if side effects of the antihypertensive agents are not tolerable, or if renal function declines, then attempts to alleviate the stenosis by PTA or by surgery are indicated. Reliable indicators of declining renal function are radiographic findings of a decrease of 10% in the length of the kidney, and laboratory findings of a decreasing creatinine clearance and an increasing serum creatinine level.[18]

Atherosclerotic lesions can be divided into two types, those involving the renal artery orifice as it passes through the aortic wall, and those involving the renal artery distal to its orifice.[20] Determining the type of lesion is important, because lesions that involve the orifice of the renal artery and the wall of the aorta are not likely to be changed favorably by PTA. In patients whose lesions involve the renal arteries away from their orifices, PTA has resulted in complete reversal of hypertension for up to two years.[21]

Fibrodysplastic lesions of the renal arteries occur most often in women who are less than 50 years old. This type of stenotic lesion usually occurs distal to the first centimeter of the renal artery. Fibrodysplastic lesions with only one or two short stenotic segments appear to respond better to PTA than those with multiple areas of involvement, and better than those involving long segments of the renal artery or its branches. In contrast to the lesions of atherosclerosis, the lesions of fibrodysplasia are much less likely to recur for periods as long as three years.[19-24] The recurrence rate with atherosclerotic lesions may be as high as 50% or even 100% after one year.

As with PTA in other anatomical locations, the major acute risks of renal artery PTA relate to perforation of the vessel with a guidewire or catheter, and to rupture of the vessel by the distending balloon. Such complications would require emergency surgery and might arise in 1% of patients. Acute renal artery occlusion may develop due to dissection of the intima or plaque, or there may be embolization or thrombosis incident to PTA-induced vascular injury. The panel believes that attempting to traverse and dilate an occluded renal artery is an investigational procedure.

A possible complication after renal artery PTA is renal failure related to the use of contrast media or to occlusion or thrombosis.[22] Renal failure secondary to the use of contrast material appears to be more frequent in patients with bilateral renal artery disease, and in those with only one kidney who already have impaired renal function, and may require long-term hemodialysis. In patients with impaired renal function, PTA should be undertaken with great caution, and there should be careful attention to hydration before and after the procedure. Also, careful monitoring is necessary after the procedure, because acute hypotension or hypertension may develop.

The panel's estimates of the range of outcomes that are possible with renal artery graft surgery and with renal artery PTA appear in Table 2. The less favorable rates with atherosclerotic lesions refer to older patients.[19-24]

Contraindications to PTA of renal artery stenosis are several, the panel believes, and include the lack of a skilled angiographer or of an immediately accessible experienced vascular surgeon; refusal of the patient to agree to surgery in the event there are complications; refusal of the patient to undergo long-term hemodialysis, if there is renal failure after PTA; absence of reliable renal vein renin studies; and total occlusion of the renal artery due either to atherosclerosis or to fibrodysplastic disease.

Conclusions and Recommendations

Percutaneous transluminal angioplasty (PTA) is a procedure that is acceptable for relieving an isolated stenosis in any of several arterial beds. In general, the technique is indicated for localized lesions that are sufficiently serious to cause symptoms of ischemia and to warrant surgical bypass grafts. In appropriately selected cases, the procedure may be as effective as surgical bypass grafting and may present less risk of mortality or other serious complication, and may have the added advantages of requiring fewer days in the hospital and of causing less pain. While the precise indications and contraindications for the use of PTA are still being defined, the AMA-CSA advisory panel agrees with the following conclusions and recommendations.

Proper patient selection and adequate experience of the operator are necessary for the patient to realize the full benefits of the procedure. The operator's experience also determines the proportion of patients that will have complications due to PTA. Long-term results of PTA in the renal arteries are less well documented than are those involving the iliofemoral and coronary artery systems. Experience with the use of PTA in treating iliofemoral lesions has accumulated for about 15 years.

Using PTA does not preclude later surgical bypass grafting. In fact, with some lesions PTA should not be used unless the patient understands the possible need for a surgical bypass procedure and agrees to undergo that procedure if necessary. PTA should be limited to one vascular bed per procedure.

Coronary artery PTA may be performed in patients with isolated lesions involving short segments. The procedure should be very selectively applied in patients with left main coronary artery stenosis, a calcified plaque, a long stenotic segment, multiple stenoses in one artery, or involvement of more than one vessel. PTA is contraindicated with a lesion that occurs at the bifurcation of a major vessel. Coronary artery PTA should be considered to be an alternative to aortocoronary bypass graft surgery. Such surgery may be necessary if PTA is unsuccessful.

Renal artery PTA can decrease a stenosis that is severe enough to impair kidney function or to cause hypertension. The procedure should be attempted only if there are meaningful differences in renal vein renin activity, if the patient's hypertension cannot be managed by medical means, or if renal function is deteriorating. The results after PTA are better with fibrodysplastic lesions than with atherosclerotic lesions.

Major complications of PTA include arterial spasm, thrombotic occlusion, embolization, intimal dissection, and perforation with hemorrhage. The panel recommends the use of heparin and nitrates before, and aspirin after, PTA procedures that involve the coronary arteries.

Because PTA is a relatively new procedure, it would be desirable to have a national registry that utilizes objective methods to evaluate the early and late results of PTA in each arterial bed.

PTA offers promise in the treatment of vascular lesions. The panel emphasizes that physicians should be aware of the risk factors associated with atherosclerosis and should advise their patients in the best management of those factors.

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Table 2

ESTIMATED RANGES OF OUTCOMES IN THE TREATMENT OF RENOVASCULAR HYPERTENSION

		Percent of Patients With		
Type of Lesion	*Method of Treatment*	*Cure (1)*	*Improvement (2)*	*Failure (3)*
Atherosclerotic	Surgery	20-50%	13-40%	5-37%
	PTA	10-40	30-70	50-80
Fibrodysplastic	Surgery	40-80	17-24	10-29
	PTA	50-80	20-40	10-40

(1) Cure: Diastolic blood pressure less than 90 mm Hg, one year after procedure and on no medical therapy.

(2) Improvement: Diastolic blood pressure less than 90 mm Hg on medical therapy, or decrease of at least 10 mm Hg one year after procedure.

(3) Failure: Neither cure nor improvement as defined above.

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Preparing to Sell Your Medical Practice

EDWARD M. STROGEN, JR. AND LOUIS V. BUCCINO, ESQ.

Since many medical practices are bought and sold these days, solo practitioners are well advised to begin considering that possible transaction several years before they actually plan to retire. Well-chosen business steps will help them realize the best financial return on their years of practice while also helping assure good continuity of medical care for their patients.

A doctor who adheres to these suggested details will fare better both economically and emotionally than those who do not.

Increase Your Gross Income

The greatest variable in a practice sale will be payment for its "goodwill value"—the expectation of continued earnings even after the owner-doctor is no longer involved. While the goodwill value will vary dramatically, ranging from zero for some specialties up towards a year's gross income for others, the values will typically be expressed as a percentage of gross income.

Therefore, a doctor might increase his ultimate practice sale price if he can increase the gross income for the last couple of years before the sale. Most goodwill values will be based upon the average gross income for the final two or three fiscal years, so the effort must be considered early. Some doctors try to pump up their final year's practice income, but potential buyers will be less convinced than by several years of consistently higher earnings.

The critical years would be those just preceding the last year of practice. For example, if a physician wishes to retire on January 1, 1988, he should expect to negotiate the sale during 1986 or early 1987. The key years for a potential successor's evaluation of his practice's volume would thus be 1984, 1985 and 1986.

One should not, of course, merely pump up gross income by artificial means. In addition to being of doubtful propriety, it would be recognized as such by a well-advised potential buyer; and it will be downgraded if it does not carry with it a comparable net income—the "bottom line." To the extent, however, that you can hold your practice at full activity, even if by bringing in a part-time associate or locum tenens, it would be financially preferable to phasing down your activity. Also, if for some reason all practice revenue did not flow through the practice's books, now is the time to change your accounting procedure. For example, if you are presently recording only the net received from a physician contractor, change your arrangement so that the gross income appears on your books, as well as the contractor's fee. This will decrease your net profit as a percentage of income but does not affect the bottom line. The advantage is that while you may only be willing to work a 30-hour week and contract out 15 hours more, the prospective buyer may desire to work 45 hours himself and eliminate the additional expense.

Identifying Your Potential Buyers

There are four classes of potential purchasers for your practice, and good business sense dictates your pursuing all of them. Let us consider each class:

1. *Colleagues in Your Region.* A doctor already in practice in your area, who might be called your colleague or your competitor, depending on your relationship, will often be the best possible purchaser of your practice. In these days of increased physician supply and competition for patients, your practice would be an ideal source for practice growth. Existing practitioners are recognizing this point more and more these days. They also recognize the "defensive" need to keep out a new, young doctor who might become more aggressive competition than you have been. Existing practitioners will thus consider taking over your practice to add to their own volume and to "protect their turf."

There is a risk to alerting colleagues to your decision. Once your intentions become public, your employees and patients may feel less secure and seek out another physician or medical practice to meet their needs.

2. *Young Physicians Out of Training.* Physicians just finishing their residencies or fellowships have traditionally been purchasers of practices for sale. They are increasingly reluctant to start their own practices in view of the developing physician "oversupply" and their levels of

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The authors are consultants affiliated with The Health Care Group, Bala Cynwyd, PA.

medical school debt, so they continue to see purchase as an attractive alternative.

Recruiting for a newly trained physician-purchaser is essentially equivalent to recruiting for a potential associate. Good clinical ability and satisfactory personality are just as important since the selling physician needs the assurance that his buyer will succeed at least enough to meet the purchase payment obligations; and one's long-standing patients deserve this quality concern as well. We estimate a well-structure practice transfer to a competent and personable successor will retain some 70 percent to 80 percent of your patients. Thus a young doctor should be able to finance your buy-out if he is carefully selected.

3. *Physicians Practicing Elsewhere.* There are an unmeasurable but significant number of potential purchasers already in practice outside of your area. Some of them may be practicing in the armed services' medical programs, and may be planning to resign and enter private practice. Others may wish to leave an unhappy association or move for personal or family reasons.

4. *Institutional Purchasers.* Finally, there is a new phenomenon: health care institutions themselves are purchasing practices. Hospitals are increasingly becoming private practice competitors, for they realize the need to control practices which will feed them admissions. Some medical school residency programs are taking over private practices to support themselves financially and to provide patients for training purposes. Some physicians have also sold their practices to area HMOs.

Institutional purchasers have one strong advantage insofar as the selling physician is concerned. Since they are tax-exempt as charitable or educational organizations, it makes no difference to them whether or not the purchase price is allocated to non-deductible "goodwill." Characterizing your pay-out as being for goodwill is typically far better tax-wise for the selling doctor. You might receive, from an institution, a price and tax package which individual purchasers cannot match.

Sell It Yourself?

The sale of your practice can be approached in two ways: a "Broker" may handle the sale, usually for a percentage of the selling price, or you can sell your practice yourself. There is no "right" choice between these two options; practices have been sold successfully in either instance. The method you choose will depend upon your willingness to devote the time and effort necessary to the sale process. The involvement of advisers or brokers, on the other hand, will depend on the physician, as well as time constraints and cost concerns. It is important to recognize, and to keep in mind, that the premium you pay for someone else to find a buyer may be offset by the income lost from time spent handling the details by yourself.

We will direct the rest of this article to the physician who has made the decision to tackle the sale of his practice on his own.

Planning

As stated at the beginning of this article, we have identified four major groups of potential buyers for your medical practice:

(1) colleagues in your area
(2) young doctors recently out of training
(3) physicians practicing elsewhere
(4) institutional purchasers

This universe of potential buyers should be aggressively informed of your proposed sale in a thorough campaign that is well-organized. Part of this informational process is deciding what written documents you should prepare for the potential purchaser. Two of those documents should be the following: (1) a narrative description of your practice and (2) a proposal to offer prospective buyers.

1. *Written Practice Description.* The description of your practice will be useful for a number of reasons: First, it will force you to think about your practice (the pros and cons) in an orderly and objective fashion *from the viewpoint of a buyer.* Consider what would be important to you if you were a possible purchaser of your own practice. Be realistic—noting both good and bad points. A serious buyer will undoubtedly recognize practice weak points and have better negotiating ammunition unless any deficiencies are raised up front. Items to address include: your specialty, practice location and its positive community aspects, size of office and type of structure, patient type (Medicare, private insurance, etc.), number of active and inactive patients, current office hours, fees charged, number and classification of employees, overhead rate, hospital affiliations and a brief description of assets to be included in the sale (i.e., office building, x-ray, equipment, etc.)

This description will also serve as the basis for getting the word out to potential buyers through letters and ads.

2. *The "Proposal."* The proposal for sale should be a simple two to three-page document that describes the transfer of the financial and operational aspects of your medical practice (and office facility, if applicable). It should not deal with the details for the buyer's or seller's protection, nor the accounting and legal procedures that may be desirable. Those details should be addressed after the agreement on the basic aspects have been reached, at least in principle. This proposal will be used to start the negotiation process once an acceptable buyer has been identified.

The proposal should include the following information:

(a) A bare-bones description of your practice with provisions to provide additional information for further discussion.

(b) A stated purchase price including a breakdown as to how the price was determined (i.e., price for real estate, furniture and equipment, goodwill, etc.). Make sure the total price is higher than your expectations in order to give yourself room to negotiate. (It may be worth your while to seek out specific tax advisers' opinions on this point.)

Also, you may consider using an independent medical practice appraiser to arrive at the price. This objective valuation will lend credibility to your asking price and prevent you from establishing a price which is too low or too high.

(c) The proposed settlement date and your willingness (if appropriate) to accept payments on an installment basis.

(d) Your role—active or inactive—in your medical practice after it is sold.

(e) The terms of any restrictive covenant you may be agreeable to that will assure the buyer of your willingness not to compete with him or her.

(f) A variety of other items such as: retention of employees in the practice after the sale; handling of medical records for retention and access; collateral (insurance, personal assets, etc.) required to secure the purchase price for you.

As soon as you have prepared these two documents—either independently or with your adviser's help—you are ready to confidently proceed with finding an acceptable buyer.

Getting the Word out and the Buyers in

No one can tell where that one best purchaser will come from, so directing your reach to a large pool of potential buyers will increase the likelihood of your success. As such, the following methods should be used in a concerted effort to reach all four classes of buyers we mentioned earlier.

1. *Word of Mouth.* Start spreading the word of your intention to sell among hospital personnel and colleagues in your specialty. Hospital administrators may be quite helpful—perhaps they may know of doctors looking for practices. In addition, the hospital may be interested in helping a new doctor settle into the area or, perchance, in buying the practice itself. Your colleagues may also be interested in purchasing it and, thus, this method could be the easiest route to a quick sale.

2. *Journal Advertising.* An abbreviated version of the practice description that you initially drafted should be placed as an ad for a number of months in several major journals of your specialty or subspecialty.

Journal ads should be drafted with some flair in order to catch the readers' eye and elicit as many responses as possible. Oversized ads with text are recommended. The difference in cost between a standard half-inch want ad and a two-inch bordered ad is so slight in relation to the subject's importance that any economy in the cost of ads would be false.

The ad may thus contain a bold heading, extra blank space above and below the first and last lines, and a centered title to attract readers' attention.

The text should request a cover letter and curriculum vitae to be sent to a box number (provided by the journal). This type of advertising will make physicians practicing elsewhere, and possibly some institutional purchasers and residents as well, aware of your practice opportunity.

3. *Training Programs.* Direct contact to chiefs of residency and fellowship training programs is often a good way to sell a practice. The practice description on your letterhead should be attached to a cover letter to the chief of *every* well-regarded training program. The effort should not be limited to a handful of programs within the practice's geographic region: the location in which a doctor trains bears no consistent relationship with where he or she may choose to practice.

The department chief will probably post the description of your practice opportunity listings. You should make sure your memo is eye-catching and readable. The doctors reading the memo's description should be invited to respond by letter to a post office box. Ask them to enclose a curriculum vitae for your initial screening review.

Screening the Buyers

After you have accomplished the preceding steps, you should have a selection of potential buyers to choose from. You will next need to pick the best candidates and determine if they will be potential purchasers. Be sure to check references. You will want to choose competent physicians with sound financial resources.

Once you have narrowed down your candidates, proceed with a telephone screening of your top choices to determine their level of interest. The potential buyers should be invited to come talk with you.

The subsequent meetings should be brief with a focus on your practice. Give the individual(s) your prepared proposal, answer all questions and indicate a slight willingness to negotiate. Be sure to prepare for meetings beforehand with counsel from your attorney and other advisers. Following the meetings you will wait for responses from the interested physicians and then accept, reject or negotiate the offers you receive. Unless you are skilled in financial matters, you should rely on your advisers in evaluating offers. A $60,000 offer with a 13% note and 75% goodwill allocation is better for most sellers than a $75,000 offer with a 10% note and 20% goodwill allocation. You want to maximize the present value of the after-tax proceeds, so do not be concerned with matching the price received by other practices which were sold in your area. Medical practices are not fungible, and therefore each sales agreement must be structured to handle the financing and tax considerations of the specific buyer and seller. The selling price is but one factor in the practice transfer and it should be evaluated along with the quality of care the buyer will give your patients.

BEHIND THE FACE OF HYPERTENSION

New evidence for central control

How a Legislative Bill Becomes Law

RAYMOND T. SULLIVAN, JR.

Preliminary Action

Prior to the opening of a legislative session, and for a limited time thereafter, members of the General Assembly may file proposed bills and resolutions in the house to which they were elected. These proposals may indicate a special concern of the legislator or may be introduced at the request of private citizens, organizations, the governor, executive department heads or other governmental bodies. Proposed bills are not filed in full statutory language, but rather state the substance of the legislation in informal, non-statutory language. Bills written in formal statutory language may be introduced only by committee. Every proposed bill which requires the expenditure of funds must include an estimate of the required cost. Bills may be jointly sponsored by Senators and Representatives, and members may cosponsor a bill originating in either house by requesting the clerk to add them to the list of sponsors.

There are two types of acts for which all bills are introduced: (1) Public Acts having to do with laws of general application; (2) Special Acts having to do with particular individuals, corporations, towns, cities or special districts.

Resolutions deal with non-statutory matters such as confirming nominations, extending congratulations or sympathy, making appointments or adopting rules for the conduct of the session. A Senate or House Resolution (SR or HR) requires action by the house of origin only. A proposed constitutional amendment is introduced as a joint resolution (SJR or HJR) and follows the legislative procedure of a bill except for different voting requirements. Resolutions are not submitted to the governor.

All bills and resolutions must receive three readings in each house before passage. The first reading takes place when the clerk of the house of origin reads the title of a bill and its reference to committee or when the house accepts a printed list of bills showing numbers, titles, sponsors and committee reference. Bills are introduced in one branch and sent after first reading to the other branch for similar action and are printed in the Journal of each branch by number and title and are then sent to committee.

The second reading is the report of the committee, and the third reading is passage or rejection of the bill by the full house.

Committee Action

The Committee separates Proposed Bills into subject categories and prepares bills on those subjects which, in its opinion, bills should be prepared. A committee may also prepare "Raised Bills" on new subjects. Committee Bills and Raised Bills are drafted by the Legislative Commissioners' Office, sent to both houses for a first reading, and then returned to their original committee for consideration. Hearings are usually held to give the public an opportunity to express its views for or against a bill. Legislators and state agency officials may be invited to express their views during the hour before the public hearing. Members can petition a committee to draft a proposed bill and schedule it for a public hearing in cases where a committee has chosen not to do so.

After the committee has considered a bill, it may:

- Issue NO REPORT. In this case the bill is considered to have failed in committee.
- Issue an UNFAVORABLE REPORT.
- Issue a FAVORABLE REPORT. When a committee votes to report a bill or resolution favorably, the chairman submits it to the Legislative Commissioners to be checked for constitutionality, correctness of reference and phraseology, general accuracy and consistency with existing statutes. The committee's report is published in the Journal. The Commissioners must transmit the bill to the house of origin within ten calendar days unless an extension has been specifically requested and granted by the Speaker of the House and the President Pro Tem of the Senate.

A bill requiring an appropriation (except for payment of claims against the state) is referred to the Appropriations Committee unless such reference is dispensed with by a two-thirds vote of each house.

RAYMOND T. SULLIVAN, JR., Assistant Executive Director Public Affairs and Legislation.

Senate and House Action

If a bill is not reported out of committee, it may be forced out for action by one of two methods: (1) If the Speaker of the House and the President Pro Tem of the Senate give written certification of the need for action, or (2) if a majority of the house in which the bill originated files a written petition with the clerk of that house within specified time limits.

After the Legislative Commissioners have delivered a reported bill back to the clerk of the house of origin, the bill is read and tabled for the Calendar; this constitutes the second reading in that particular house.

When the bill has received an unfavorable report, it receives only one printing on the Calendar. The house then usually approves a motion to reject the bill, and the action is noted in the Journal. No further action is taken unless requested by a member of that house.

Each favorably reported bill receives a file number and is placed on the Calendar in the order received. The bill is then printed for the files of the members of both houses. Copies must be in the members' files for two session days before action can be taken.

A bill to which no objection is expected may be designated by the majority and minority leaders of the house in which it originated to be put on the Consent Calendar. When ready for action the bill can be passed on motion without discussion unless a member objects and requests that it be transferred to the regular Calendar. Removal to the regular Calendar will not result in delay of consideration.

NOTE: Any bill not printed and in the files of the members may be acted upon if the Speaker of the House and President Pro Tempore of the Senate certify in writing the necessity for an immediate vote. A copy of the bill must appear on the legislators' desks.

General Debate

General debate on a bill is in order after it receives a third reading. Members of the house acting on the bill may offer amendments before the final vote. In this case, amendments must be voted on separately before vote on the bill.

A majority of each house constitutes a quorum to do business. A simple majority vote is needed for action (with the exception of constitutional amendments, bills providing for redistricting the General Assembly and constitutional convention bills). A roll-call vote can be ordered by one-fifth of the members present.

A bill receiving a favorable vote in the house in which it originated is held over for one day for a motion to reconsider. If the bill is not reconsidered, it is sent to the other house for a second reading and placement on the Calendar of that house.

Amendments approved in the second house must be returned to the first for its approval. In the event of disagreeing action between the two houses, a committee-of-conference may be appointed for the purpose of reaching agreement.

Submission to the Governor

After a bill has passed both houses, it is transmitted to the Governor for approval or disapproval:

- A bill becomes law when the Governor signs it.
- A bill becomes law when the Governor fails to sign it within five days provided the General Assembly is in session, or within fifteen if it has adjourned.
- A bill vetoed by the Governor is returned to the house in which it originated with his objections. To override the Governor's veto, a two-thirds vote of the members of each house is required for a bill to become law.

(Public Acts become effective on October 1st following passage, unless otherwise specified. Special Acts become effective upon approval, unless otherwise specified.)

Constitutional Amendments

A constitutional amendment may be adopted in a single legislative session if approved by three-fourths of the total membership of each house. It it is approved in one session by at least a majority but by less than three-fourths, it must receive a majority vote of approval in the session following the next election to be adopted. A constitutional amendment is subject to the approval of the voters at referendum at the next even-year general election following passage.

Month in Washington

President's Budget Again Would Cut Medicare/Medicaid

As has each budget since his first election, President Reagan's fiscal 1986 budget proposal includes substantial cuts in Medicare and Medicaid.

For Medicare, some $4.2 billion in first-year savings would be achieved by increasing beneficiary premiums, reducing funding for graduate medical education, and freezing payments to hospitals, physicians, clinical labs, nursing homes, and other providers. The federal Medicaid contribution would be capped to save $1 billion in 1986.

All told, the proposed budget reduces an estimated $45.2 billion Medicare payment hospitals in fiscal 1986 by about $2.7 billion; a projected $17.8 billion expenditure for physician services would be cut by about $500 million. About 63% of Medicare savings would come from the hospital cuts and 12% would flow from the extension of the current physician fee freeze.

The proposals, which are part of a $330 billion budget for the Department of Health and Human Services, would hold Medicare cost increases to 2% and Medicaid increases to 3% at a time when enrollees in the two programs are expected to climb by 2% and 1.7% respectively.

The proposals include:

- A 12 month extension of the physician fee freeze enacted last summer and scheduled to end October 1. This would apply to both participating and nonparticipating physicians. Estimated fiscal 1986 savings are $500 million.
- A freeze on diagnosis related groups prices for hospitals. Expected savings are $1.8 billion in 1986.
- A cap on payments for direct costs of medical education projected in 1986 to shave about $150 million from payments that currently total about $1 billion.
- The elimination of the current doubling (from 5.795% to 11.59%) of the Medicare adjustment for indirect medical education costs. Estimated savings from the plan are $695 million in fiscal 1986.
- Staged-in increases in Part B premium increases so that by 1990, premiums would cover 35% of program costs. Medicare income would be increased by $334 million in fiscal 1986.
- Cap the fiscal 1986 federal payment to states for Medicaid benefits at $22.2 billion or about $1.3 billion less than projected under current law. A $300 million hardship fund would be created for states that had large cost increases despite efforts to curb costs.

Congressional criticism of the physician fee freeze centers primarily on the belief that it breaks a promise to participating physicians who were to have had potentially higher fee increases at the end of the freeze. HHS Secretary Heckler said she doesn't believe the freeze breaks a promise to the participating physicians and Health and Care Financing Administration head Carolyn Davis, Ph.D., said the freeze delays but does not deny the larger increases.

* * * *

Medical Education Cuts Attacked

Medical educators and students say they are "outraged" by a Reagan Administration budget proposal that would "wipe out" federal support of health professions' education and congressional health staffers have told the Administration that the proposal is "politically impossible."

The widely-predicted provision in the just-released fiscal 1986 budget plan followed a presidential veto of health manpower reauthorization legislation late last fall after Congress had adjourned. Conventional wisdom is that the veto might otherwise have been overridden, and committees with manpower jurisdiction are preparing to reintroduce manpower legislation.

The educational assistance programs the President seeks to terminate include grants for special training programs, assistance to financially disadvantaged and minority students and schools, and nurse training.

No new federal capital would be allocated for Health Professions Student Loans (HPSL), but an estimated $67 million in revolving loan funds administered through 1,400 health professions and nursing schools would remain in circulation. The current $250 million ceiling on Health Education Assistance Loans (HEAL) would be lowered to $100 million.

Prepared by the Washington, D.C.
Office of the American Medical Association

The budget proposal also would end the National Health Service Corps scholarship program and would reduce funds for NHSC members already in underserved communities by about a third—from $75 million in 1985 to $50 million in FY86. The budget cuts occur despite an expected increase in the number of NHSC practitioners in the field—from 3102 in 1985 to 3507 in 1986. Federal officials say the funding shortfall can be made up by continuing efforts to encourage more NHSC scholars to repay their obligation through private practice rather than as federal corpsmen.

In other manpower budget provisions, the maternal and child health block grant would be funded at its 1985 level of $478 million; funding for the Indian Health Service would be reduced by nearly $100 million; health planning funds would be eliminated and federal staff associated with manpower programs would be reduced by the equivalent of about 1000 full-time positions, a primary care block grant that currently offers an alternative to categorical funding for community health centers would be expanded and "probably" made mandatory.

In justifying the decision to end "federal subsidies" to the health professions, the budget documents point to a "projected national surplus" of physicians and nurses.

Representatives of the medical profession said, however, that the cuts in professional training support are exacerbated by proposed restrictions on guaranteed student loans for all students of higher education. The real impact of the proposal will be to influence the makeup of the medical student population and specialty and geographic distribution rather than to curtail the overall physician supply, they added. James H. Sammons, MD, Executive Vice President of the American Medical Association, said the cuts could "endanger the quality of health care in the United States."

* * * *

Despite HCFA Budget Cuts, Physician DRG Studies Continue

Federally-funded research into physician payment options will continue despite President Reagan's proposal to cut Medicare-and-Medicaid-related research funds by a third in the fiscal 1986, Health Care Financing Administration officials say.

The proposal to cut HCFA's research and demonstration budget from $33 million in fiscal 1985 to $22 million in fiscal 1986 could force the agency to scale back on studies in some other areas, however. It could also curtail research in the remainder of 1985.

If accepted by Congress, the budget reductions would come just as HCFA officials are struggling to complete a host of congressionally-mandated studies on the extension and refinement of Medicare's diagnostic-related groups (DRGs) payments for hospitals. Some studies, including one on the treatment of capital costs in DRG payments, are already overdue. Others, such as a recommendation on the "advisability and feasibility" of extending DRGs to inpatient physician services, have had the deadline moved up—from December 31, 1985 to July 31.

As a result, HCFA Administrator Carolyne Davis, PhD, told reporters at a budget briefing that the 1986 budget recommendation would require the agency to "target" its research efforts on physician payment and the extension of prospective pricing to other parts of the system. Although the research reductions can be justified as part of a larger effort to trim the federal deficit, she added, the cuts do represent a "definite shift."

The announcement of the fiscal 1986 budget request coincided with a solicitation of bids for Medicare and Medicaid studies and demonstrations to be funded in the remainder of 1985. Carried in the January 30 Federal Register, the solicitation outlines areas in which HCFA has an interest and signals the Administration's desire to move away from a system that depends on the number of services provided to one that limits the government's liability to some predetermined amount.

One area in which HCFA is "extremely interested," the solicitation says, is "reforming physician payment methods." Demonstrations could involve the examination of the impact of a Medicare voucher on physician participation, incomes, specialty and location. Or they might center on prospective payments for physicians.

Prospective payment might combine hospital and physician payments, it suggests, or it might package all physician services through areawide budgets, competitive bidding, preferred provider organizations, or risk-sharing with Medicare carriers such as Blue Shield plans.

Other studies of interest to HCFA include those aimed at: finding a better way to adjust within DRGs for differences in the severity of the patient's condition; comparing the medical condition and treatment of patients in physicians offices with those in hospital outpatient or ambulatory settings; examining the effect of hospital DRGs on skilled nursing facilities, home health agencies, rehabilitation facilities, and swing bed services, expanding private risk-sharing for long-term care costs; promoting home care by the family or other community arrangements; designing a new payment for end-stage renal disease patients; and improving the formula used to compute prospective payments to Medicare HMOs.

* * * *

Some Preliminary Results Reported

If federal policymakers want to pay physicians by diagnosis, they should start with surgery and make payments to hospital medical staffs rather than to individual physicians, a Massachusetts research firm advised Medicare officials in February.

The advantage of this approach, according to the Center for Health Economic Research, is that it would discourage a growth in physician services said to be responsible for about 40% of recent increases in Medicare Part B expenditures for medical services. Half of all Medicare physician payments—but only a fourth of hospital admissions—would be affected.

Based on 900,000 1982 Medicare claims in Michigan, New Jersey, North Carolina, and Washington, the CHER study is the most extensive look yet at how Medicare's diagnosis-related groups (DRGs) hospital pricing system could be extended to physicians. As such, it is expected to be a critical element in a Health Care Financing Administration report to Congress on the "advisability and feasibility" of physician DRGs.

The CHER study is, however, only a part of a body of HCFA-funded research just coming into final form as the agency rushes to meet July's deadline for the report which originally was not due until December. Reported at a conference sponsored by HCFA and Project HOPE, the CHER work is one of a number of studies that raise concerns about physician DRGs.

Two Boston University MDs concluded, for example, that even if refined, DRGs aren't likely to accurately reflect the costs of a particular case. A Virginia firm found that a physician DRG was "at best not unthinkable." And a Project HOPE study warns that adoption of physician DRGs might permanently sidetrack efforts to encourage the growth of HMOs and other capitation plans.

Physician reactors disputed the assumption that physician DRGs will curtail an increasing volume of services and questioned the wisdom of any plan that asks physicians to move from the role of patient advocate to businessman. Several speakers suggested that hospital medical staffs are not well-enough organized to receive and redistribute the DRG payment.

* * * *

Durenberger Calls For Medicare Incentives For Nonsmokers

Now shed of the pipe that had become his hallmark, Minnesota Republican Senator David Durenberger wants Medicare beneficiaries to follow his example.

To encourage them, the Senator is proposing that elderly smokers pay higher Medicare premiums than nonsmokers. Such a policy, he argued, would follow private insurers "lead in rewarding those who choose to avoid smoking which unquestionably increases the risk of illness." It could also make a "positive contribution" to "seniors' health" and to the "health bill of the nation."

Called the Medicare Cost Incentives for Non-Smokers (S-357), the bill is part of a package of three measures that Durenberger introduced to "explore the many ways Medicare can be restructured to incorporate the possibilities of prevention." A second bill would raise the Medicare Part B deductible and then permit certain preventive health services to count toward the deductible. The third would fund five Medicare demonstrations to test Medicare coverage of preventive services.

Professional Liability High On States' Agendas

Nineteen states expect to consider medical malpractice legislation in 1985 and seven states see this as one of the top three health issues they will face this year, according to a new survey by the National Conference of State Legislatures.

The survey ranked care of the medically indigent as the top issue in the states in 1985 and it found several other issues—including long term care and Medicaid reimbursement of physicians and hospitals—that outscored malpractice in terms of the number of states that saw it as a major issue.

Nevertheless, an NSCL official said he believes that medical malpractice "will be on the platter in every state" in the country.

All told, the states anticipate deliberations on about 39 malpractice bills. Thirteen legislatures are likely to consider general limits on malpractice awards and a bill introduced in Colorado would limit malpractice recoveries whenever a second opinion had been obtained. Thirteen states will consider placing ceilings on lawyers fees while 12 may require arbitration of medical malpractice suits. Colorado, Delaware, Florida, Kansas, Michigan, Utah, and Wisconsin ranked malpractice as one of the top three issues the legislatures would face in 1985.

The NSCL survey, which was conducted in November and December of 1984, found that states will consider more than 585 health care cost containment bills in 1985. Forty states responded to the survey.

State Medicaid programs and physician services to these patients also will absorb a great deal of the legislators' attention. Thirteen states identified Medicaid hospital and physician care as top priorities in 1985. Eleven states are expected to consider requiring or encouraging Medicaid recipients to get all their care from a primary care MD. Six (Alabama, California, Colorado, Indiana, Minnesota, and Oregon) are likely to debate proposals that would require Medicaid patients to go only to physicians under contract to the state. Six states will probably consider contracting with hospitals for services to Medicaid patients. Eight may require prior authorization for all hospital care.

* * * *

National Health Policy Group Recommended

The Catholic Health Association has urged President Reagan and Congress to create a 15-member national commission on health policy.

CHA President John Curley told the Washington press corps that the commission's goal would be to "stop the nation's reliance on short-sighted, stop-gap measures that control health care costs without solving the problems that escalate costs."

Commission members, who would serve for three years, would be picked by President Reagan, the Speaker of the House and the President pro tempore of the Senate. Each would name five members consisting of a physician, a health care administrator, another health professional and two members from other fields such as insurance, labor, law, and business.

* * * *

Medic Alert Plans Major Expansion

The Medic Alert system, whose members wear metal bracelets to signal potentially hazardous medical conditions, intends in the next two years to develop a medical abstract that could be the basis for a worldwide computerized medical records system.

The two-million member foundation will work with the Defense Department and with medical specialty groups in an effort funded through a $140,000 grant from the Robert Wood Johnson Foundation.

Medic Alert officials, who outlined their plan at a Washington press conference, say their primary interest is to improve and expand their own emergency warning system but they believe that a highly mobile population has created new demands that go far beyond the original Medic Alert concept. They suggest that the AMA/GTE Medical Information Network would be an ideal network for their proposed system but they add that the abstract they are developing will be part of the public domain—available to a wide range of organizations that have an interest in their plan.

* * * *

GAO Cites Government Lack in Medicaid Program

The Health and Human Services Department should issue regulations or use financial penalties to improve states' identification of Medicaid patients who also have private insurance or other coverage, according to the General Accounting Office.

A GAO report based on six state Medicaid programs confirmed an HHS estimate that Medicaid may be spending $500 million to $1 billion a year for medical care to Medicaid patients who have other coverage, but it maintained that HHS has not taken all the steps it could to improve state performance in this area. State and federal governments shared in the losses since the federal government contributes from 50% to 78% of total Medicaid spending per state.

In its investigation of Medicaid programs in California, Maryland, Oregon, Pennsylvania, Texas, and Washington. GAO identified several ways in which states could improve their procedures for identifying which Medicaid recipients have other coverage such as private health and auto insurance, workmen's compensation, or military health benefits.

One GAO recommendation would require health care providers to seek payment from other identified insurers before billing Medicaid. Others call on the states to ask Medicaid recipients more specific questions to identify possible insurance coverage beneficiaries may not even be aware of; to ask beneficiaries for the other insurers' name and the policy number; to compare Medicaid files with other data sets such as lists of state employees; and to screen claims such as for broken bones that might be associated with accidents covered by liability insurance.

For the federal government the report recommends two options: (1) strengthen regulations governing state recoveries of other insurance benefits; or (2) reduce federal Medicaid payments to states by the amount that federal officials could have been collected from other insurance programs.

HHS Inspector General Richard Kusserow responded that HHS is working with states to enhance Medicaid collections from other insurers. He claims that stiffer regulation of state collection efforts would not work unless they were associated with financial penalties which could not be imposed without new legislation.

* * * *

NIH Consensus on Travelers' Diarrhea

Rapid institution of treatment can shorten travelers' diarrhea from three to five days to 30 hours or less in most people, according to a National Institutes of Health (NIH) panel of experts.

Travel to high-risk areas of Latin America, Africa, the Middle East, and Asia is associated with 20% to 50% of diarrhea in travelers from more developed countries. Careful dietary and hygenic practices will prevent some, but not all, cases.

Before leaving the US the travelers should obtain two types of drugs: an anti-motility agent and an antimicrobial agent. By obtaining them in advance, the traveler can avoid buying potentially dangerous over-the-counter products and can begin prompt treatment if needed.

For mild diarrhea, the traveler should take an anti-motility agent. Drugs such as diphenoxylate or loperamide were recommended by the NIH panel. Bismuth subsalicylate, which works somewhat slower but is also effective, may also be used. The products come in convenient dosage forms and provide prompt, although temporary, symptomatic relief.

For more serious cases, an antimicrobial drug should be used. These cases—manifested by three or more loose stools in an 8-hour period, often accompanied with nausea, vomiting, abdominal cramps, fever, or blood in the stools—can be shortened to 1 or 1½ days with this type of drug. The NIH panel recommended combining 160 mg trimethoprim and 800 mg sulfamethoxaxole or taking 200 mg trimethoprim alone, twice daily.

The President's Page

A Solution

In mid March I attended a meeting with a well known political personality in Connecticut. Its purpose was to apprise him of medical political problems in our state so that he might be able to formulate some policy positions for future reference. Two items were discussed, the Medicare freeze and the medical malpractice crisis in Connecticut. The bulk of the time was spent discussing the latter subject. I came to the meeting expecting to educate someone and left being educated in modern politics.

As physicians, we are very naive when it comes to the political process. We feel that right is on our side and we are not interested in grass roots involvement because "right" will triumph. The gentleman in question is a modern politician, well versed in the media and its uses. Without any prompting he proceeded to paint a scenario which organized medicine must follow if it is to be successful in accomplishing what is best for our patients and ourselves. He perceived the apathy which exists in the medical profession when it comes to socio-economic-political problems. His solution involves money and the use of the media.

I have often thought what might be accomplished if the physicians of this state contributed adequate amounts of money to lobby for legislation, established a public relations department with sufficient funds to bring our message to the people both in our offices and through the media, organized physicians statewide to speak on medical subjects and to appear on television and radio talk shows, and launched a year round program rather than one which is active only when the legislature is in session.

The question invariably raised is the cost. A single assessment of $250 per physician would raise $1 million. An assessment of $100 per physician, per year for three years would raise even more. With this type of money and with more direct doctor input we would be able to get our many messages across to the public.

An example of a message not being heard by our patients is the cost, both direct and indirect of malpractice insurance. An example of a direct cost which occurs in my office is the fact that an average of $200 of every surgical fee is paid toward malpractice insurance premiums. It also has been reported that only 17 cents of the premium dollar is returned to the injured party. This means that 83 cents goes for legal fees, both plaintiff and defense as well as administration of the insurance. I am certain the public is unaware of these facts.

The indirect costs of defensive medicine are reputed to be 15 billion dollars nationally which, if extrapolated to Connecticut amounts to 180 million dollars. This information needs to be disseminated.

For those who feel that lawyers are responsible for the malpractice problem, let us not sit back and complain but rather take up the cudgel, make our positions clear and face the lawyers in public.

We have a problem; let's approach it as we would a serious illness in one of our patients.

Joseph S. Sadowski, M.D.
President

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Reflections on Medicine
A Third Way?

ROBERT U. MASSEY, M.D.

Two factors appear more likely than DRG's and technological advance to change the course of medical care in the Nation before the century is out: the aging of the population and the increasing numbers of women in medicine. Both forces are pushing generally in the same direction; both may, if seen aright, be beneficent.

We shall, one way or another, adapt our institutions and our professions to the inevitable changes of population structure; those changes, like the changing weather of the seasons, come on slowly enough to allow for accommodation, the baleful warnings of the doomsayers to the contrary.

In the matter of caring for the elderly the good nursing homes have manifestly outdistanced the rest of us. Their staff members know that looking after the well-being of older men and women takes, in addition to the three theological virtues of faith, hope, and charity, a great deal of wisdom and reliance upon the special gifts of many responsible individuals. They begin at the beginning with education and prevention; they look after their patients, remembering always that they are members of families and neighborhoods; because each family is unique and each patient one of a kind, they are always trying out something new, their solutions are ingenious. They provide companionship, home care, day care, recreation, rehabilitation, residential care, skilled care, terminal care. They pick up the pieces when the hospitals, pressured into squeezing their patients into shorter and shorter lengths of stay, must discharge the sick before they are well. And in all of this reaching out and taking pains, they are driven not by the imperative to market their wares and drive off their competitors, but by their belief that theirs is a special responsibility to help the disabled or distressed to make their way along the same road which most of us will one day travel.

What is only beginning to be understood is that the model nursing homes, and there are a number around, are following a paradigm, or creating one, which might stand as a pattern for the whole health enterprise; they are not unlike the balanced hospital community envisaged by Thomas McKeown 20 years ago.[1] They have evolved a system well adapted to answer to a set of patient needs; mostly the system has not been planned out, but rather has grown incrementally and pragmatically. Those who work at it, especially in the good places, are driven by the impulses like those that once enlivened the Good Samaritan. Profit, product line, market share, and bottom line are not words in their vocabulary; they may recall what happened to those who bought and sold in the Temple.

More women in medicine may help this development along. When a third or half of the physicians are women, we may find more interest in managing programs for the care of those who need them than in corporate restructuring and going after the other fellow's market share. Women physicians may help to restore harmony between doctors and nurses and to settle the differences which have been allowed to trouble relations between the two professions. Not that professional rivalry itself matters to anyone except those wasting their energy in the battle, but purposes get lost, ideals lose their power, and patients may be hurt.

By its nature the care of the elderly requires cooperation between the professions and cooperation between institutions; it is by turns, or all at the same time, nursing care, doctoring care, rehabilitation, counselling, listening, befriending, and leaving alone. It is more like nursing than it is like doctoring, especially the doctoring in the fast-paced tertiary care hospital or surgical center. The disabled elderly with their many and complicated needs, most of which will not go away this side of death, require the kinds of skill, wisdom, and patience which physicians have tended to forget during the past three or four decades. High and even halfway technology works and it keeps getting better. But managed health care of the disabled elderly may require that we relearn the art of doctoring; the nurses and the women doctors may, unless they undergo some kind of transformation, help us to do that. In the process we may avoid the caricature of medicine as a business; we may find the *via media* between competition and regulation.

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ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Alcohol, Law and Public Policy: The Reform Era

JOSEPH M. HEALEY, J.D.

In my last column, I identified several key characteristics of the traditional anglo-american legal policy toward the use and abuse of alcohol. Within this framework alcohol abuse was viewed as a sin, a defect of the will for which the individual deserved to be punished. The policy emphasized punishment and deterrence rather than prevention and rehabilitation. The decade of the 1960's was an important period for judicial and legislative reform. An alternative conceptual framework was slowly integrated into a revised public policy. This framework continues to dominate discussion of current controversies. This column will examine several aspects of the development of this framework.

Three major legal cases focussed attention on the problems of chronic alcoholics. In the first case, a 59 year old man who had been convicted of public intoxication 200 times during a 35 year period and who had spent nearly two-thirds of his life incarcerated for alcohol-related offenses challenged the constitutionality of his most recent conviction.[1] In the second case, a 62 year old man who had been arrested 70 times during a 30 year period challenged the constitutionality of his most recent conviction.[2] In the third case, a man arrested 100 times over a 19 year period challenged the constitutionality of his most recent arrest.[3] In each case, the defendants argued that alcoholism should be viewed as a disease which causes involuntary intoxication and involuntary public appearances while intoxicated. The involuntary nature of the defendant's behavior negated one of the essential elements of a crime. Under such circumstances, the accused should not be convicted of a crime.

The cases present a depressing but not atypical portrait of the chronic alcoholic. Under the traditional legal view of alcoholism, punishment and incarceration would be justified. The inadequacy of such a policy can be seen in the repeated arrests and imprisonment of the men in the three cases without affecting their alcohol problems. The alternative proposed in the three cases would recognize alcoholism as a disease needing treatment rather than punishment. Such an approach would replace the moralistic medieval view of the world reflected in the traditional framework.

In the first case, the Court of Appeals for the Fourth Circuit held that the eighth amendment prohibition against cruel and unusual punishment prevents the conviction of a homeless alcoholic for his public intoxication. In the second case, the Circuit Court of Appeals for the District of Columbia held that a homeless alcoholic's public intoxication does not constitute voluntary action and is therefore not punishable. The third case was a complex 5-4 Supreme Court decision in which, though the conviction was upheld, the new conceptual framework was accepted by a majority of the Justices:

> " . . . five of the nine Justices agreed that alcoholism is a disease, that an alcoholic drinks involuntarily as a result of his illness, and that an alcoholic who was either homeless or who could not confine his drunkenness to a private place for some other reason could not be convicted for his public intoxication. Powell's conviction was upheld by a 5-to-4 vote, however, because the record failed to show that he was homeless or otherwise unable to avoid public place when intoxicated."[4]

The move toward the acceptance of the disease model of alcoholism and toward the development of appropriate preventive and rehabilitation strategy was reflected in massive legislative activity throughout the United States. The effect was the decriminalization of public intoxication and the development of therapeutic alternatives to the criminal law. A major area of concern, however, is the protection of society from injuries caused by the problem drinker. As has recently been pointed out:

> "The field of alcohol abuse and alcoholism approaches another crossroad. The fifty years after Prohibition witnessed a humane understanding for treatment of the alcoholic. That effort should and must continue. However, the great challenge now—indeed, one the public is demanding—is how to effectively minimize the enormous burden of harm of the third major health problem in America. The knowledge and tools to do so do exist, as crude as they may be. Does America have the energy and the will to begin in ernest? Or is the nation destined by inaction, ineffective efforts, or emotion to repeat the errors of the past?"[5]

This subject will be the focus of next month's concluding column.

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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Connecticut Medicine

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Editorials

Organ Harvesting: Soft-Tech

A dead organ, a viable organ. These are the currency of organ harvesting and transplantation. A dead organ is of limited utility—its minerals destined to enter nature's own recycling schema. A viable organ offers the promise and hope for a given patient of a productive life. Organ harvesting involves a different form of recycling. Its essentials involve a reclamation of organs from those who have not and making them available to others that they may have.

How fortunate we are in the State of Connecticut in having two major transplantation centers. The extraordinary skill of the surgical teams at these centers makes available to patients we serve the very real hope of successful organ transplantation. For the other hospitals in the State, all of whom have ready access to these transplant services, there is an opportunity to become actively involved in the procurement of organs.

At Lawrence and Memorial, we began formalizing our organ acquisition endeavors in January of 1979 with the establishment of an Organ Harvesting Committee. This Committee is composed of physicians, nurses and clergy. Our initial meeting agenda involved education, establishment of policy, and review of legal ramifications. From that point on the Committee became actively involved in the establishment of an orderly process for the acquisition of organs. We are conscious of the fact that since most patients who are potential organ donors are accident victims, we are dealing with families distraught with unanticipated grief. We are also aware that simultaneously elsewhere in the State, families are huddled around the bedside of a critically ill patient awaiting an organ transplant and these family members are experiencing anticipatory grieving in the event that the surgical transplant team is unable to secure a viable organ for transplantation purposes. In this interaction between death and life, physicians, nurses and clergy can rediscover their roots as caring professionals as each contributes to the overall healing process.

In the high-tech environment of artificial hearts and transplantation, soft tech endeavors such as organ harvesting rekindle in the health professional compassion for those in need. In a way we are helping to preserve the professional's capacity for caring for later generations.

What is now needed is for all community hospitals to become involved by establishing formal Organ Harvesting Committees. In addition, we look forward to community leaders of uncommon vision becoming involved with the many intricacies of organ donation. Simultaneously it is hoped that the leaders of our legislative bodies will view our modest endeavors as a cause worthy of their support. Community hospitals, civic leaders and legislators working in concert toward a common goal of organ harvesting and transplantation can collectively provide immeasurable benefits in assuring that appropriate viable organs will be recycled patient-to-patient to the benefit of all.

David P. Lauler, M.D.

Chairman, Department of Medicine;
Director of Medical Education,
Lawrence and Memorial Hospitals;
Clinical Associate Professor of Medicine,
Yale University School of Medicine

The Need for Good Communication Skills in Medicine

On January 21st, we met with Fairfield County legislators. A large turnout of our elected representatives joined members of the Board of Trustees and the FCMA Committee on Legislation for a lively discussion. The main topics discussed were seat belts and tort reform. They heard our concerns and our proposed solutions. We

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Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

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learned of their problems in dealing with our needs while representing the varied points of view of their constituencies.

There was a good exchange of ideas and we all learned from this dialogue. I don't know how much we accomplished. Only time will tell. But the important thing is that we communicated and, I think, we communicated well. I expect all of us to continue this communication as specific legislative bills arise.

The need for communication extends to our patients. In recent years the AMA has spent a great deal of money on attempting to improve the physician's image with the public. More recently, the State Society spent a large sum on a professional survey concerning what patients think of their doctors. Unfortunately, the survey told us only what we already knew.

Currently, the CSMS Council is considering, through its Committee on Public Affairs, the expenditure of $30,000 for a public information media program. The costs for newspaper ads are high, radio time, very high, and T.V. announcements, unbelievably high, and the positive gain is questionable.

We all know that it is we, the practicing physicians, as individuals, who are the more efficient and most inexpensive creators of public opinion. I suspect many of us do not communicate with our patients as well as we should. Modern medical technology has a lot to do with this.

When I was in medical school 30 years ago, we were taught that the most important part of the examination was the history; second, the physical; and way down at the bottom of the list was the laboratory. But, then, we did not have 5% of the tests that we have now. As a result, the more intimate part of an examination—the history and physical—is downgraded and predominant is the impersonal aspect of the medical work-up which is often turned over to strangers—the consultants and their technicians.

Patients, and often their doctors, do not ask what did the examination show, but they ask what did the "tests" show? And when the "tests" fail to find the magic answer, the patients, without adequate explanation, may interpret the doctors as saying that there is nothing wrong with them while the patients know very well that something is wrong. Our modern technology increases the patient's expectation of exact diagnosis and curative treatment. When our magic fails to reveal the answer, we need to take our patients into our confidence. Often we can assure them, plus ourselves, that even though we have not arrived at a definite diagnosis, we can assure them that the possible serious diagnoses probably have been ruled out.

Much of this communication and explanation to the patient is the duty of the primary care physician. But, the consultants are not off the hook. Too often, the consultants do their thing and say, "This patient's problem is not within the province of my specialty" and think the job is done.

Whether general practitioner or super specialist, we are all physicians. As medicine advances, we need to rise above technology and communicate with those who influence our destiny. We must communicate with our fellow physicians and, most of all, with our patients who depend upon our magic for their security and peace of mind.

Robert P. Ragusa, M.D.

President
Fairfield County Medical Association

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Practice Environment of Young Physicians

Recent entrants into the medical profession are confronted by a much more competitive environment than earlier generations of physicians had to face. Not only has the number of physicians increased sharply in recent years, but so has the number and types of providers. As a result, young physicians may find it difficult to establish a practice. Data indicate that:

- Average 1983 net income after expenses but before taxes is $82,600 for all nonfederal, patient-care physicians in the first five years of practice, $112,300 for those in the sixth through the tenth year, and $113,700 for physicians with more than ten years experience.
- The net income profile for specific specialties follows a similar pattern: rising until about twenty years of experience and then declining.

Call For Manuscripts

A future issue of *Connecticut Medicine* is to be dedicated to the Connecticut Tumor Registry on the occasion of the Fiftieth Anniversary of its founding through the efforts of CSMS. Our registry is the longest continuous tumor registry in the world, and the most widely quoted. In recognition of the anniversary, the International Association for Cancer Research will hold its World Meeting in Hartford this December, at the invitation of Connecticut's Commissioner of Health.

The Guest Editor of the special issue of the Journal is Jack Cole, M.D., Ensign Professor of Surgery, Yale University School of Medicine (785-5479). Physicians and other researchers using Connecticut Tumor Registry data in current cancer studies are invited to contact Dr. Cole concerning submission of manuscripts or abstracts for possible publication in the special issue.

Arthur W. Knowlton, M.D., Chairman
CSMS Cancer Coordinating Committee

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

VISION THERAPY AND LEARNING DISABILITY

To the Editor: I am not only surprised, but also very concerned that a journal of the stature of *Connecticut Medicine* would publish a misleading article, "Vision Training and Learning Disorders," by Arnold A. Heiger, M.D.,[1] a pediatrician, with the majority of references quoted from the optometric literature and not from the medical literature.

The abstract indicates a possible role for orthoptics in the therapy for learning disabilities, with an illustrative case presentation. A major complaint about the reported success of optometric vision therapy concerns the use of anecdotal case reports, without controls. Dr. Heiger presented an anecdotal report of a two-and-a-half year old girl, with "clumsiness in gross motor abilities," who improved her ability to focus by wearing eyeglasses. This is not a case of learning disability, as the title of the article suggests, nor was the child receiving vision therapy nor orthoptic therapy. The author does not reveal the refractive error of the child, nor the power of the lenses prescribed by the optometrist. How can this case possibly be used to illustrate the abstract of the article, when in fact this young girl was only placed in eyeglasses? Furthermore, a control patient was not described, of similar age and refractive error who did not have "clumsiness in gross motor abilities" to determine if the control child would attend to tasks with better attention if she wore similar eyeglasses.

Dr. Heiger describes in a negative manner the 1981 position paper of the American Academy of Ophthalmology and the American Association for Pediatric Ophthalmology and Strabismus[2] concerning the relationship of learning disabilities and vision. In July 1984, the journal, *Pediatrics*,[3] published a more extensive statement on Learning Disabilities, Dyslexia and Vision jointly written by the Committee on Children with Disabilities of the American Academy of Pediatrics, the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology. This paper clearly states the lack of scientific evidence for using vision therapy in the treatment of learning disability. This paper had been approved by these groups in January and February of 1984 and was readily available for reference before Dr. Heiger's paper was published in *Connecticut Medicine.*

In July 1984 in *Pediatrics*,[4] a special article from the Department of Psychology at Pennsylvania State University by Richard Metzger, Ph.D., and David Werner, M.D., reported on the use of visual training for reading disabilities. In an extensive review of the ophthalmologic, optometric, and psychological literature, with 35 references quoted, these authors found no evidence to support the assumption that visual training provided any effective treatment for reading disabilities.

The use of plus or hyperopic lenses may be useful in a child who has accommodative esotropia to reduce the focusing effort and allow the eyes to become straighter and to provide binocular vision, when possible. However in a child without esotropia who has a normal refractive error, there is no need for a "learning lens" or "plus lens" as Dr. Heiger describes, because children possess excellent accommodation and do not need the crutch of weak hyperopic lens for assistance in focusing. Plus lenses usually become essential in the adult population at approximately forty years of age when presbyopia occurs and assistance for focusing then becomes necessary with a bifocal or a reading glass.

Dr. Heiger concludes that the pediatrician has difficulty advising parents regarding the position of optometric care in the area of learning disabilities. Any pediatrician or any physician or parent of a child with learning disabilities who reads the position statement of the American Academy of Pediatrics, the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology as well as the excellent paper by Metzger and Warner, can only conclude that after treating any correctable ocular defects, that the treatment for learning disability must rest in the domain of educators and not eye doctors.

Paul R. Mitchell, M.D.

Newington, CT

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3. Learning Disabilities, Dyslexia and Vision. Pediatrics 74:150-151, July 1984.
4. Metzger RL, Warner DW: Use of Visual Training for Reading Disabilities: A Review. Pediatrics 73:824-829, June 1984.

LAWYERS CONCERNED FOR LAWYERS

To the Editor: This letter is to inform any and all medical personnel within the state of Connecticut of the existence of a group known as Lawyers Concerned for Laywers. We are an affiliate of the Connecticut Bar Association whose function is to reach out to the attorney who might be afflicted with alcohol and/or substance abuse problems. We are not a disciplinary agency but rather function to share the experience, strength, and hope of alcoholics who have recovered or are in the process of recovering. We practice confidentiality, discretion, and anonymity and our only purpose is to reach out.

If anyone in the medical profession encounters attorneys and feels that they could recommend that their patient, friend, or acquaintance at least inquire of this committee, then we would be pleased to meet or arrange for any follow-up that seems appropriate. Anyone interested in making contact with the committee should contact the below listed addressee.

Igor I. Sikorsky, Jr.

Secretary, Lawyers Concerned For Lawyers
111 Pearl St., Hartford, CT 06103

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
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"Why your investments aren't as successful as you are."

By Dr. S.R. Sarantos

Face it. Few problems are as complex as the management of your practice, money and taxes. And few health care practitioners have the extensive specialized expertise necessary for success in precisely these disciplines. Expertise which is vital to achieving financial growth, and, ultimately, independence.

As one of the health care practitioners who has been fortunate enough to gain these crucial financial skills, I'd like to share a few observations on why so many otherwise successful practitioners don't have similar success when it comes to their investments.

Strategies to make your earnings grow

A successful practice alone is not enough to guarantee your financial independence. That requires a careful balance of prudent, disciplined tax planning and professional management of your retirement assets.

Too many of you have relied far too much on the stock market...and paid the price for its unpredictability. Why assume such risk–when you can pursue a conservative, non-stock market approach that provides for a reliable, real rate of return? A diversified portfolio based on short-term guaranteed investment vehicles, as well as real estate investments designed specifically for retirement plans, can satisfy both your immediate and future financial needs.

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193rd ANNUAL MEETING
# of the
CONNECTICUT STATE MEDICAL SOCIETY
May 8, 9, 1985
Park Plaza Hotel
155 Temple Street
New Haven, Connecticut

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A MESSAGE FROM THE PRESIDENT

The 193rd Annual Meeting of the Connecticut State Medical Society will, once again, afford an opportunity for members of the Society to participate in the educational and economic activities of the Society.

On Wednesday, May 8, the House of Delegates will meet in open session, at which time the reports of officers, committees and various resolutions introduced from county associations and individual members will be acted upon. Election of officers and committees for 1985-86 will also take place at this time. The membership-at-large is invited and urged to participate, through the reference committee hearings, where most of the business coming before the House will be discussed. Come and let your voice be heard.

The inauguration of the new President, William A. Whalen, Jr., M.D., of Willimantic, will take place at the House of Delegates meeting and will be followed by a reception for the President immediately following the close of the meeting.

A very timely program will be presented on Thursday, May 9; one which should be of interest to all physicians. A symposium will be presented in the morning on "Computers in Medicine" and individual papers on Dementia, Genetic Engineering and Aids will be presented in the afternoon. In addition to obtaining new information on these important subjects, it is also an opportunity to obtain CME Category I credits.

This meeting is planned for the benefit of the entire membership, and it is hoped that you will make every effort to attend in order to keep abreast of the times, both in your Society and your practice.

Joseph S. Sadowski, M.D.

GENERAL INFORMATION
READ CAREFULLY

REGISTRATION

The registration desk will be located on the mezzanine floor of the hotel and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket when and only if they register.

PARKING

There are parking facilities at the hotel and in the immediate surrounding area.

TELEPHONE

Telephone messages will be received at New Haven, 772-1700.

LUNCHEON

Luncheon will be served in the ballroom on the mezzanine floor and ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.

HOTEL ACCOMMODATIONS

Persons who wish to stay overnight at the hotel should make room reservations as soon as possible. Please indicate in your letter that you are attending the Connecticut State Medical Society Meeting.

PROGRAM

The House of Delegates will be held on May 8th and the scientific program will be held on May 9th. The scientific program will be concentrated in one day, May 9th. The general program will be held in the ballroom between 10:30 A.M. and 4:00 P.M. and the section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:00 P.M. in the rooms listed in the program.

PRESIDENT'S INAUGURATION

The inauguration of the new President will take place at the House of Delegates meeting on May 8th, at about 4:30 P.M. All members are invited to attend the inauguration. The annual dinner will be replaced with a reception following the close of the meeting.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL UNLESS OTHERWISE INDICATED

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING.

ANNUAL MEETING OF THE HOUSE OF DELEGATES
WEDNESDAY, MAY 8, 1985
BALLROOM MEZZANINE

Presiding:
Lawrence B. Ahrens, M.D., Wethersfield, Speaker of the House
Mehdi S. Eslami, M.D., Waterbury, Vice Speaker of the House

12:00 REGISTRATION OF DELEGATES
Light sandwich buffet will be available

12:30 CALL TO ORDER
REPORTS OF OFFICERS, COMMITTEES, OTHERS
OLD AND NEW BUSINESS
ADDRESS OF THE PRESIDENT—JOSEPH S. SADOWSKI, M.D., HARTFORD
ELECTION OF OFFICERS AND COMMITTEES
INTRODUCTION OF GUESTS
PRESENTATIONS AND AWARDS
INAUGURATION OF THE NEW PRESIDENT—WILLIAM A. WHALEN, JR., M.D., WILLIMANTIC
INAUGURAL ADDRESS
ADJOURNMENT
RECEPTION TO FOLLOW

GENERAL SCIENTIFIC PROGRAM
THURSDAY, MAY 9
MORNING SESSION

8:15 REGISTRATION—MEZZANINE

8:30-10:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

10:00 INTERMISSION TO VISIT EXHIBITS

BALLROOM WEST

10:20 CALL TO ORDER AND WELCOMING REMARKS
WILLIAM J. WHALEN, JR., M.D., WILLIMANTIC
President, Connecticut State Medical Society

Presiding:
James D. Kenney, M.D., *New Haven*

SYMPOSIUM ON COMPUTERS IN MEDICINE

10:25 INTRODUCTORY REMARKS
JAMES D. KENNEY, M.D., NEW HAVEN; Associate Dean for Graduate and Continuing Education, Yale University School of Medicine

10:30 COMPUTERS IN MEDICINE: AN OVERVIEW
DAVID STAGG, Ph.D., NEW HAVEN; Director, Bio-Medical Computing Unit, Yale University School of Medicine

11:00 COMPUTERS IN DIAGNOSTIC IMAGING
JOHN C. GORE, Ph.D., NEW HAVEN; Associate Professor, Diagnostic Radiology, Director NMR Research, Yale University School of Medicine

11:30 COMPUTERS IN HOSPITAL MANAGEMENT: PATIENTS, DOCTORS, INFORMATION AND RESOURCES
ROBERT T. SADOCK, M.D., NEW HAVEN; Physician Administrative Associate, Yale-New Haven Hospital

12:00 EXPERT CONSULTATION SYSTEMS IN MEDICINE
PERRY L. MILLER, M.D., Ph.D., NEW HAVEN; Assistant Professor of Anesthesiology, Yale University School of Medicine; Department of Anesthesiology, Yale-New Haven Hospital

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON—Ballroom East

AFTERNOON SESSION

Presiding: Ramon N. Kranwinkel, M.D., *Danbury*

2:00 WHAT'S NEW IN DEMENTIA
ROBERT E. HARBAUGH, M.D., NEW HAMPSHIRE: Chief Resident of Neurosurgery, Dartmouth Hitchcock Medical Center, Hanover

2:30 CLINICAL APPLICATIONS OF GENETIC ENGINEERING
SALLY SHULMAN, M.D., FARMINGTON; Fellow in Genetics, Instructor in Pediatrics, University of Connecticut Health Center

3:00 AIDS: IMPLICATION IN YOUR PRACTICE
EILEEN HILTON, M.D., DANBURY; Director, Infectious Control Committee, Danbury Hospital; Assistant Clinical Professor of Medicine, Yale University School of Medicine

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in Program)

THURSDAY, MAY 9
MEETINGS OF SECTIONS OF THE SOCIETY
MORNING SECTION PROGRAMS

SECTION ON EMERGENCY MEDICINE

8:30 A.M. College Room A

President: Richard A. Lavely, M.D., *New Haven*

SUDDEN DEATH: EPIDEMIOLOGICAL CONSIDERATIONS
JONATHAN B. BORAK, M.D., NEW HAVEN; Chairman, Department of Emergency Medicine, Hospital of St. Raphael

LIGHTENING INJURIES
MARY ANN COOPER, M.D., HARTFORD; Chairman, Department of Emergency Medicine, St. Francis Hospital & Medical Center

IMPROVED COSMETIC EFFECT OF LACERATION REPAIR BY EXCISION OF EDGES
RICHARD A. LAVELY, M.D., NEW HAVEN; Director, Temple Urgent Care Center

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SECTION ON FAMILY PRACTICE

8:30 A.M. Trianon Room

President: Neil H. Brooks, M.D., *Rockville*
Secretary: Donald D. Timmerman, M.D., *Middletown*

CONTEMPORARY MANAGEMENT OF HYPERTENTION
WILLIAM MILLER, M.D., FARMINGTON; Assistant Professor, Department of Family Medicine, University of Connecticut/St. Francis Hospital Medical Center

ERIC JACKSON, Pharm. D., FARMINGTON; Assistant Professor, Department of Family Medicine, University of Connecticut/St. Francis Hospital Medical Center

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SECTION ON PEDIATRICS

8:30 A.M. College Room B

President: E. Maurice Wakeman, M.D., *Guilford*
Secretary: Katherine Prioli, M.D., *Norwich*

NUTRITION FOR SPORTS AND LIVING
JOSEPH H. ZELSON, M.D., NEW HAVEN; Associate Clinical Professor of Pediatrics, Yale University School of Medicine

SECTION ON PHYSICAL MEDICINE AND REHABILITATION

8:30 A.M. Plaza Room

President: Charles R. Marshall, M.D., *Norwalk*
Secretary: Jerrold N. Rosenberg, M.D., *New Haven*

REHABILITATION MEDICINE

CHARLES R. MARSHALL, M.D., NORWALK; Assistant Professor Clinical Rehabilitation Medicine, Columbia College of Physicians and Surgeons

MEDICARE REIMBURSEMENT FOR REHABILITATION SERVICES

CAROLYN K. DAVIS, HARTFORD; Director, Health Care Financing Administration

LOW BACK PAIN IN INDUSTRY

JERROLD N. ROSENBERG, M.D., NEW HAVEN; Director, Department of Physical Medicine and Rehabilitation, Hospital of St. Raphael

HEAD INJURY REHABILITATION AND COST TO INSURANCE INDUSTRY

PHILIP B. ARNOLD, M.D., NEWINGTON; Director, Department of Medicine and Rehabilitation, Newington Children's Hospital

NEW TECHNOLOGY IN REHABILITATION

FRANCIS X. PALERMO, M.D., WALLINGFORD; Director, Department of Physical Medicine and Rehabilitation, Gaylord Hospital; Clinical Instructor in Medicine, Yale University School of Medicine

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SECTION ON PSYCHIATRY

8:30 A.M. Colt Room C

President: Cornelis Boelhouwer, M.D., *Hartford*
Secretary: Thomas J. Conklin, M.D., *Hartford*

CARE OF THE ALZHEIMER'S PATIENT: A 1985 UPDATE

ALAN SIEGAL, M.D., NEW HAVEN; Robert Wood Johnson Clinical Scholar; Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

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AFTERNOON SECTION PROGRAMS

SECTION ON ANESTHESIA

4:00 P.M. Parkview Hilton Hotel, Hartford

President: William D. Conrad, Jr., M.D., *West Hartford*
Secretary: Gerald S. Piserchia, M.D., *Glastonbury*

4:00 EXECUTIVE MEETING
5:00 BUSINESS MEETING
6:00 SPEAKER AND DINNER

SECTION ON INTERNAL MEDICINE

3:30 P.M. College Room D

President: Morton Bender, M.D., *New Haven*
Secretary: Robert M. Stark, M.D., *Greenwich*

HYPERTENSION–UPDATE ON NEW STUDY

HENRY R. BLACK, M.D., NEW HAVEN; Associate Professor of Medicine, Director of Hypertension Clinic, Yale University School of Medicine

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SECTION ON NEUROSURGERY

4:00 P.M. College Room B

President: Franklin Robinson, M.D., *New Haven*

BUSINESS MEETING

(See listing for May 10th program elsewhere in this program)

SECTION ON OBSTETRICS AND GYNECOLOGY

4:00 P.M. Trianon Room

President: John M. Gibbons, M.D., *Hartford*
Secretary: Edwin J.T. Moore, M.D., *Waterbury*

PRENATAL SCREENING FOR BIRTH DEFECTS USING MATERNAL SERUM A.F.P.

ROBERT M. GREENSTEIN, M.D., FARMINGTON; Professor of Pediatrics, University of Connecticut Medical School and Health Center

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SECTION ON OPHTHALMOLOGY

4:00 P.M. Plaza Room

President: Turpin Rose, M.D., *Danbury*
Secretary: Peter C. Donshik, M.D., *West Hartford*

CATARACT SURGERY UPDATE

CHARLES KELMAN, M.D., NEW YORK CITY; Assistant Clinical Professor, New York Medical School

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SECTION ON PATHOLOGY

4:00 P.M. Governor Eaton Suite

President: Dante B. Cannarozzi, M.D., *Waterbury*
Secretary: Edwin M. Clayton, M.D., *New London*

PALEOPATHOLOGY IN SOUTH AMERICAN MUMMIES–UPDATE 1985

ENRIQUE GERSZTEN, M.D., RICHMOND; Professor of Pathology, Medical College of Virginia

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SECTION ON RADIOLOGY

4:00 P.M. College Room C

President: Nancy Allen, M.D., *Waterbury*
Secretary: Harold Moskowitz, *Hartford*

ROUTINE MAMMOGRAPHY–ITS USE AND INDICATIONS

NANCY ALLEN, M.D., WATERBURY; Staff Radiologist, Waterbury Hospital

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SECTION ON UROLOGY

4:00 P.M. College Room A

President: James F. Walsh, III, M.D., *Bridgeport*
Secretary: Haik Kavookjian, Jr., M.D., *Stamford*

BUSINESS MEETING

ELECTION OF OFFICERS

STUDENT SECTION

4:30 P.M. College Room E

ELECTION OF OFFICERS

BUSINESS MEETING

POSTGRADUATE PHYSICIAN SECTION

4:00 P.M. Ballroom West

SECOND CONNECTICUT RESIDENTS SYMPOSIUM ON CANCER

ALL PHYSICIANS WELCOME

Sponsored by: Connecticut Chapter: American College of Surgeons
Connecticut Society of American Board Surgeons, Inc.

Presiding: Edward Dunn, M.D., *Waterbury*

4:00 PRESENTATION OF WINNING PAPERS WRITTEN BY RESIDENTS ON MULTIDISCIPLINARY TOPICS RELATING TO CANCER

ELECTION OF OFFICERS

6:00 RECEPTION—Trianon Room

7:00 DINNER—Trianon Room
GUEST SPEAKER: PETER J. DECKERS, M.D., HARTFORD; Director of Surgery, Hartford Hospital

(This program also supported by the Connecticut Chapter of the American Cancer Society and the Cancer Coordinating Committee of the Connecticut State Medical Society.)

IMPORTANT—PLEASE NOTE

The following Sections of the Society will not be meeting on May 9. The program, date and time follows:

SECTION ON DERMATOLOGY

May 8, 1985

12:00 Noon Stratford Inn, Stratford

President: Donald R. Greene, M.D., *Branford*
Secretary: Laurence A. Sibrack, M.D., Danbury

MICROSCOPICALLY CONTROLLED SURGERY—TWENTY YEARS EXPERIENCE
PERRY ROBINS, M.D., NEW YORK CITY; Dermatology Department, New York University Medical Center

SECTION ON OTOLARYNGOLOGY

May 8, 1985

9:00 A.M. Ramada Inn, North Haven

President: John W. Cavo, Jr., M.D., *New Britain*
Secretary: Gordon Strothers, M.D., *New Haven*

9:00 REGISTRATION

9:30 EVOLUTION ON NOTCHED INCUS
ROGER E. WEHRS, M.D., TULSA; Staff of St. Francis Hospital and Hillcrest Hospital, Tulsa, Oklahoma

10:15 BREAK

11:00 MENIER'S DISEASE—THE SHUNT OPERATION
DAVID F. AUSTIN, M.D., CHICAGO; Associate Professor of Otolaryngology, University of Illinois

12:00 LUNCHEON

1:00 MIDDLE EAR SURGERY WITH HOMOGRAFTS
ROGER E. WEHRS, M.D.

1:45 BREAK

2:15 COLUMELLAR TYMPANOPLASTY
DAVID F. AUSTIN, M.D.

JOINT MEETING

SECTION ON NEUROSURGERY
CONNECTICUT SOCIETY OF NEUROLOGICAL SURGEONS, INC.

May 10, 1985

4:30 P.M. Fitkin Amphitheater
Yale-New Haven Hospital, 333 Cedar Street, New Haven

WILLIAM B. SCOVILLE MEMORIAL LECTURE

EXTRACRANIAL OCCLUSIVE VASCULAR DISEASE
THORALF M. SUNDT, JR., M.D., ROCHESTER; Professor and Chairman, Department of Neurosurgery, Mayo Clinic, Rochester, Minnesota

Note: The CSMS Section on Neurosurgery will hold its business meeting on May 9th at 4:00 P.M. at the Park Plaza Hotel, New Haven.

SPECIAL NOTICES
CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

As an organization accredited for continuing medical education by the Affiliation Committee for Continuing Medical Education, Yale University School of Medicine certifies that this program is acceptable for Category 1 credit as specified by the American Medical Association for the Physicians Recognition Award. Credit is granted in this category on an hour for hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for five and one half hours of prescribed credit for the general lectures and the family practice section meeting, and one and one half hours of elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

THE CONNECTICUT STATE MEDICAL SOCIETY
acknowledges with thanks a program grant received from Geigy Pharmaceuticals, Summit, New Jersey.

Our exhibits contribute to the value of our assembly by presenting goods and services of interest and importance to physicians. Personal visits to the booths will increase your understanding of the materials and programs on display.

TECHNICAL EXHIBITS

Accu-Rite, Inc., Wallingford, Connecticut
American Express Co., New York City
Ayr Insurance Agency, Inc., New Haven, Connecticut
Blue Cross and Blue Shield of Connecticut, Inc., North Haven, Connecticut
Clay Adams, Parsippany, New Jersey
Connecticut Medical Insurance Company, Wallingford, Connecticut
Data Systems of Connecticut, Milford, Connecticut
Hoechst-Roussel Pharmaceuticals, Inc., Somerville, New Jersey
National Medical Corporation, Trumbull, Connecticut
Pro Med Systems, New Haven, Connecticut
Quality Care, Bridgeport, Connecticut
W.B. Saunders Company, Philadelphia, Pennsylvania
U.S. Army Medical Department

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*
Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

COUNCIL MEETING

Thursday, February 7, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahrens, Alisberg, Bobruff, Czarsty, Fabro, Freedman, Friedberg, James, Kamens, McDonnell, Mendillo, Orphanos, Reyelt, Jr., Robbins, Sadowski, Sweet, Whalen, Jr. and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), and Mr. Coffey (HCMA).

Absent were: Drs. Ahamed, Beck, Bonner, Canzonetti, Dardick, Doctor, Kaess, Petrie, Ragusa, Scheer, Schwartz, Seide, Sullivan, Jr., Villa and Waldron.

Reports From Physicians Serving on State and Federal Agencies

Dr. Eslami provided a comprehensive chronology of the Magnetic Resonance Imaging (MRI) Task Force of the Statewide Health Coordinating Council (SHCC) along with its resultant Findings and Proposed Recommendations which had been previously distributed. The proposal will now go before the Governor and if approved then on to the Commission on Hospitals and Health Care (CHHC). The MRI Task Force intends to produce regulations for implementation of Phase II by summer.

Dr. Van Syckle commented that there has been concern expressed at the HSA-V in Waterbury, in the area of need for Long Term Care Nursing Home Beds. The HSA-V data indicates a pressing need for additional beds while regulatory reports support the opposite contention.

Dr. Czarsty noted that the Report on Special Act 84-4, An Act Concerning Provider Lock-Out From the Medicaid Program (before the Council as information only), had been reviewed at the last Liaison Committee with the Department of Income Maintenance. The program came as a result of the Medicaid Cost Containment Task Force Report to the General Assembly and is mandated by the federal government. Several committee members found that the Report contained obvious errors and DIM staff said it would correct them and bring it back to the Committee at its next regularly scheduled meeting.

Mr. Tomat reported that Governor O'Neill will proclaim February 14, 1985 as Dr. Robert Jarvik Day in Connecticut. Dr. Jarvik, a native of Stamford, is the inventor of the artificial heart. Ceremonies are planned for that day in Stamford and Hartford.

CPRO

Dr. Whalen, President of CPRO, reported that they have been reorganizing their board and committee structure during the last month. Pre-Admission Certification and Pre-Operative Review are very interesting projects. During the past month CPRO has spent considerable time constructing the Private Review Section and addressing the problem of Agreement to Review Surgi-Centers as they begin to appear on the scene. He also noted that CPRO has moved to their new headquarters in Meriden.

Dr. Kamens presented a brief description of his recent experiences as the new medical director of CPRO. He emphasized the "peer review concept" of CPRO by stating that denials are made by physicians only and that professional personnel act only upon the criteria and parameters established by physicians. The alternative is to have fiscal intermediaries step in. He noted that CPRO is the only physician sponsored PRO (20 nationally out of 50) which will have an internal quality assurance system and an educational system for the reviewers.

Finally, Dr. Whalen indicated that neither the AMA or the Rand Corp. had been selected as the Super PRO.

Report of the President

Joseph S. Sadowski, M.D., reported on a recent meeting held with the Insurance Commissioner regarding Connecticut General's interest in a preadmission certification program. Commissioner Gillies has not yet rendered a decision.

Report of the Executive Director

Tim Norbeck reported on three separate items:

a) Tort Reform

Two representatives have introduced a tort reform package which includes legislation to limit contingency fees, provide for periodic payments, eliminate the collateral source rule, impose penalties on those bringing frivolous suits and to limit noneconomic damages. The Trial Lawyers, however, have also introduced bills to broaden the Statute of Limitations. Mr. Norbeck reported that he and Ray Sullivan had met with Senator Upson, the Chairman of the General Law Committee who had introduced such legislation, and learned that the senator favored a one-year extension of the present three-year statute. The CSMS position has been opposition to any extension of the three-year limit and this was reaffirmed by the Council.

b) D-P-T Vaccine

Mr. Norbeck mentioned how the present shortage of DPT vaccine related directly to the malpractice crisis. He reported that only Lederle was selling the vaccine to the public because the other two makers (Wyeth and Connaught) could not find an insurer *at any cost.* The Lederle liability coverage is shaky at best since a conglomerate of twenty-five companies presently insures them and the contract is up for review in June, 1985. There are claims of almost $4 billion relating to the vaccine which date back to the sixties, and the defense of these suits costs from $150,000 - $500,000 each. Only 20% - 30% of each award actually reaches the patient, and the current dollar demands of DPT lawsuits against Lederle alone are two hundred times greater than the firm's total sales of the vaccine in 1983.

Following discussion of the vaccine situation, it was VOTED that the information contained in the report be transmitted to each legislator, if possible, before the next meeting of the Council, so that every legislator would have received the information prior to the legislative reception planned. This information should be used to illustrate what could happen if physicians, pharmacists, etc were unable to obtain malpractice insurance.

c) AARP

Mr. Norbeck reported that he had addressed the New Haven, Westville Chapter of the American Association of Retired Persons on Monday, February 4, 1985, pertaining to health care costs and related subjects. He mentioned that most questions focused on the Medicare program and assignment, and that he was able to correct many misunderstandings about the issue. Six more visits with AARP chapters are planned in the immediate future.

Issue of Physicians and High Technology

After discussion, it was VOTED to recommend to the CSMS House of Delegates for approval the Conflict of Interest Guidelines as developed by the AMA Judicial Council:

1. the physician has an affirmative ethical obligation to disclose to the patient or referring colleagues his or her ownership interest in the facility or therapy prior to utilization;
2. the physician may not exploit the patient in any way, as by inappropriate or unnecessary utilization;
3. the physician's activities must be in strict conformance with the law;
4. the patient should have free choice either to use the physician's proprietary facility or therapy or to seek the needed medical services elsewhere; and
5. when a physician's commercial interest conflicts so greatly with the patient's interest as to be incompatible, the physician should make alternative arrangements for the care of his patient.

Life Members

It was VOTED to receive for information the following names of Life Members:

E. Arthur Barry, Jr., M.D.,	Moosup
Dovell N. Bonnett, M.D.,	Greenwich
John W. Gerster, M.D.,	Greenwich
James P. Moriarty, M.D.,	Stamford
David C. Morley, M.D.,	Greenwich
Robert D. Murphy, M.D.,	Wethersfield
Charles H. Rosenberg, M.D.,	Stamford
Rolando R. Ruiz, M.D.,	Danbury
Daniel P. Samson, M.D.,	Thomaston

Miscellaneous

New York Times Article — January 17, 1985

Guy W. Van Syckle, M.D., discussed a recent article in the New York Times which was distributed to the Council. He expressed concern over the implications in the article and statements attributed to unidentified AMA sources. It was suggested in the article that a stronger national peer review program would alleviate the malpractice problem and that the AMA would facilitate in "getting patients into the hands of physicians who get good results."

It was VOTED to authorize the Chairman of the Council to send a letter to the AMA Executive Vice President expressing the concerns of the CSMS Council and asking for details and clarification of the AMA role.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on February 7, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

IN MEMORIAM

BISHOP, COURTNEY C., Yale University School of Medicine, 1930. Dr. Bishop was a general surgeon in the New Haven County area since 1937. He served in the U.S. Military from 1942-1946. Dr. Bishop was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 1985 at the age of 79.

BOWEN, FRANCIS, University of Maryland Medical School, 1942. Dr. Bowen was an internist in the Hartford County area since 1946. He was on the staff of St. Francis Hospital and Medical Center. After retiring from private practice in 1974, he was employed by the state Veterans Home and Hospital in Rocky Hill, where he served as a commissioner of the facility for the past two years. Dr. Bowen was a member of the Hartford County Medical Society and the Connecticut State Medical Society; died November 24, 1984 at the age of 67.

CLARKE, WINTHROP I., Harvard Medical School, 1941. Dr. Clarke was an ophthalmologist in the New Haven County area since 1942. He served his residency at Yale New Haven Hospital and was later on the staff at Yale. During World War II, Dr. Clarke served in the U.S. Army Medical Corps. Dr. Clarke was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 12, 1985 at the age of 68.

COGSWELL, LAWRENCE, Harvard Medical School, 1933. Dr. Cogswell was an internist in the Hartford County area since 1936. He joined the staff of Hartford Hospital, where he served until his retirement in 1983. Also, he was assistant medical examiner. Dr. Cogswell was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 10, 1984 at the age of 79.

COUCH, FRANK H., Yale University School of Medicine, 1930. Dr. Couch was a psychiatrist in the Middlesex County area since 1934. He was a clinical instructor of neurology at Yale and director of Cromwell Hall from 1937 to 1956. Dr. Couch also was chief medical consultant to the Bureau of Disability Determination for the Social Security Administration from 1957 to 1970. He served as president and secretary of the Middlesex County Medical Association and was past treasurer of the Connecticut State Medical Society. Dr. Couch was a member of the Middlesex County Medical Association, the Connecticut State Medical Association and the American Medical Association; died January 19, 1985 at the age of 80.

DETORA, ALBERT M., Boston University School of Medicine, 1940. Dr. DeTora was a general practitioner in the Tolland County area since 1942. During World War II, he was a captain in the U.S. Army Medical Corps. He was also affiliated with Johnson Memorial Hospital, Stafford Springs. Dr. Detora was a member of the Tolland County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 24, 1985 at the age of 70.

GILES, NEWELL W., University of Vermont Medical School, 1921. Dr. Giles was an ophthalmologist in the Fairfield County area since 1925. He was director of ophthalmology at Stamford Hospital and St. Joseph's Hospital and was on the consulting staff at Norwalk Hospital. Dr. Giles was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 31, 1985 at the age of 88.

GRANGER, DONALD, University of Pennsylvania School of Medicine, 1954. Dr. Granger was a neurologist in the Fairfield County area since 1959. He was associate professor of neurology at the Yale University School of Medicine and chief of neurology at Bridgeport Hospital where he was also director of the electroencephalography laboratory he began in 1965. Dr. Granger was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died January 19, 1985 at the age of 55.

MILLARD, DONALD H., Georgetown, 1946. Dr. Millard was an orthopedic surgeon in the Fairfield County area since 1953. He was vice president of medical services at Greenwich Hospital and former assistant chief of its medical staff. Dr. Millard was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 25, 1984 at the age of 62.

PELLA, JUAN, University of Havana Medical School, 1942. Dr. Pella was a psychiatrist in the Middlesex County area since 1958. He was a member of the Middlesex County Medical Association and the Connecticut State Medical Society; died August, 1984 at the age of 71.

ZELSON, CARL, Washington University Medical School, 1930. Dr. Zelson was a pediatrician in New York City from 1934 until his retirement in 1975. He was a professor of pediatrics and director of nurseries at New York Medical College and was a staff member of New York Hospital, Harlem Hospital, Flower Fifth Avenue Hospital and Danbury Hospital. Dr. Zelson was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 23, 1984 at the age of 79.

Trade Union For Physicians?

Naugatuck Valley Medical Society has a special announcement for readers of *Connecticut Medicine.* It is sponsoring a lecture by Dr. Sanford Marcus to be given at Woolsey Hall in New Haven at 7:00 P.M., April 23, 1985.

Dr. Marcus is well known for his advocacy of "trade unions" for physicians and is head of the 15,000 member *Union of American Physicians and Dentists.* This organization has had a 27 percent increase in its membership in the past year.

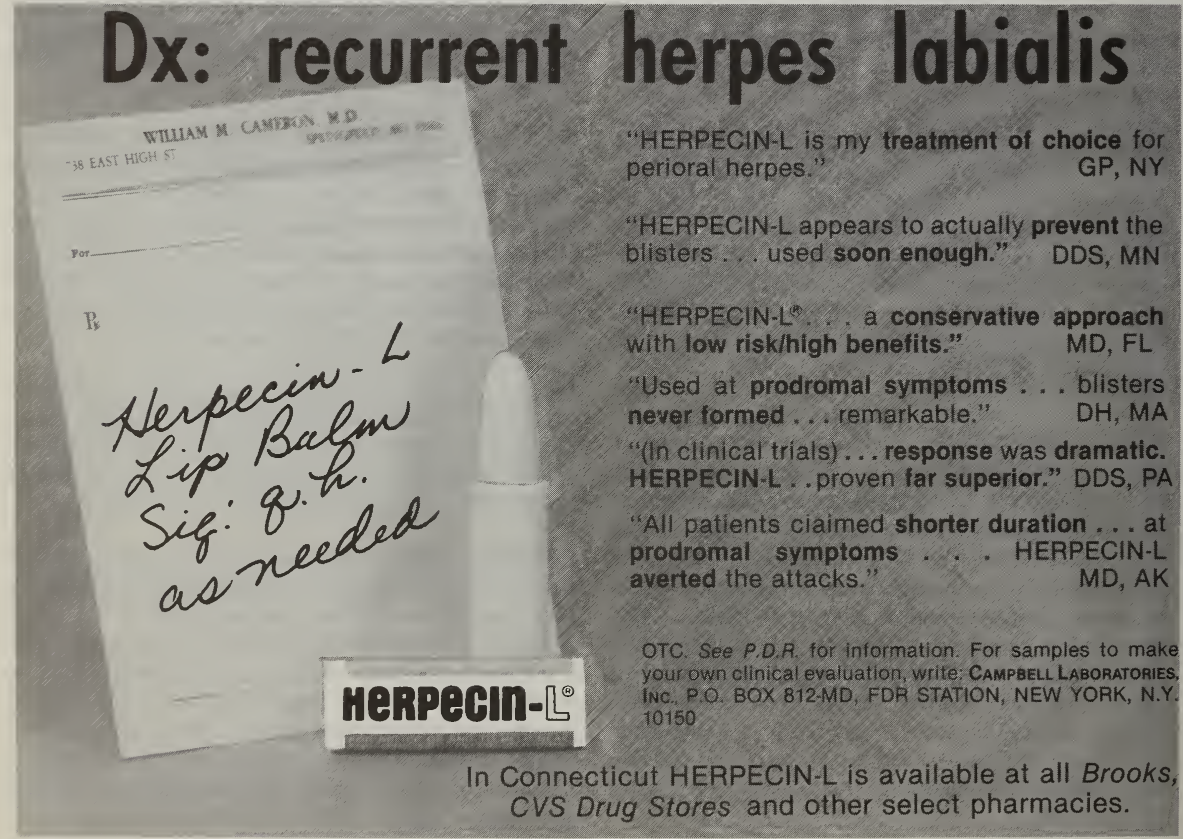
Dr. Marcus' views concerning the disintegration of the private practice of medicine and the physician/patient relationship are outlined in an extensive article in a recent issue of the *New England Journal of Medicine.*

It is felt that the point of view that Dr. Marcus has to offer may be very refreshing and innovative in the sense that physicians to this point really have lacked the solidarity and the unity which is implied in the organization of which he is President.

The Sponsoring Committee offers an invitation to all those who are interested in protecting their future.

A Contribution of $5.00 per person is necessary to cover the cost of the lecture and associated expenses; it is Dr. Marcus' express desire that physician's spouses attend this meeting. Checks should be made payable to the Naugatuck Valley Medical Society and sent to Carol Heavens, Griffin Hospital, Department of Radiology, 130 Division Street, Derby, CT 06418.

The pre-publication demand for accommodations has been brisk and it is requested that you respond as soon as possible.



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In Connecticut HERPECIN-L is available at all *Brooks, CVS Drug Stores* and other select pharmacies.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Farmington Valley, CT. Full time emergency physician needed immediately for walk-in treatment center. Opportunity for full partnership. Write CSMS, c/o EM/JR.

Full and part-time emergency room opportunities available for qualified primary care physicians in Central CT and Windham county. For information and application contact the recruitment department at 1-800-645-4848.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

EMERGENCY MEDICINE/FAMILY PRACTICE

Cromwell, Connecticut seeks high quality physician for Ambulatory Care, Freestanding Walk-in Medical Center. Position available for full and part-time. Emergency Medicine and or Family Practice physician desired with strong communication and marketing management skills. Reply with C.V. and cover letter stating availability and salary requirements to: Gail Brown, Medical Center Consultants, 2279 Grand Island Blvd., Grand Island, New York, 14072.

FAMILY PRACTICE

Board certified physician seeks associate to join well-established, expanding family practice, partnership available. Located in medium-sized central Connecticut community, ½ hour from Hartford. Modern 250 bed community hospital, coverage available, no obstetrics. Contact Anne Sondek, Four-CN Vermont Street, Buffalo, New York 14213, (716) 884-3700.

BE/BC Family physician to join two in a thriving private practice. Full hospital privileges. New office. Some pediatrics. No OB. Beautiful shoreline community. Excellent schools. Call, coverage, benefits very favorable. Residency precepting available. Start July 1985. Reply, P.O. Box 224, Old Lyme, CT 06371.

FAMILY PRACTICE/INTERNAL MEDICINE

Family Practitioner or Internist, Newington, CT, to practice medicine in a small State psychiatric hospital, ten minutes from Hartford. A 130 bed facility, accredited and certified, provides acute/intermediate psychiatric treatment. Position available April 1, 1985. Salary is commensurate with experience and training. Excellent benefit package. Connecticut license required. Send resume to Arnold W. Johnson, M.D., Chief of Professional Services, Cedarcrest Regional Hospital, 525 Russell Rd., Newington, CT 06111. AA/EEO.

Family practitioner or internist needed immediately as third MD in a Southeastern Connecticut practice. Salary on first year and partnership starting the second year. Send CV to 26 Lafayette St., Norwich, CT 06360.

INSTITUTIONAL MEDICINE

Emergency physicians and primary care specialists needed for busy freestanding emergency centers located in Connecticut. Attractive salary and fringes plus early ownership. Send CV to Box 1142, Farmington, CT 06034.

INTERNAL MEDICINE

Growing, federally qualified HMO in Southwestern CT seeks BC/BE Internist. Emphasis on personalized, cost-effective, medicine. Competitive salary, comprehensive fringe benefits, teaching appointments to university-affiliated hospitals. Submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Connecticut Health Plan, 4000 Park Ave., Bridgeport, CT 06604. Telephone (203) 371-1534.

PRIMARY CARE

Physicians—Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

PRACTICE FOR SALE

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

Internal Medicine/Cardiology practice for sale; Northern Connecticut; close to Hartford and Springfield, MA. Flexible financial arrangements. Write to SALE/JR, c/o CSMS.

RADIOLOGY

Radiologist wanted part-time for general diagnostic radiology in private office practice in Waterbury area. All replies confidential. Write CSMS c/o RAD/AA.

PHYSICIAN WISHING TO LOCATE IN CONNECTICUT

ALLERGY/IMMUNOLOGY

Availability negotiable. Presently in practice. Age 31. Nat'l bds. AB cert. (PED); AB elig. (ALL & IMM). MD. University of Vermont; Int. and Res., Columbia Presbyterian Medical Center; Fellowship, University of California, San Francisco, CA. Prefers group or associate type practice (Allergy/Immunology) in a medium to large-sized community. Write, David J. Valacer, M.D., 42 Wachusett Ave., Shrewsbury, MA 01545.

DERMATOLOGY

Feb. '85. Licensed in Connecticut. Presently in practice. Age 35. FLEX. AB cert. MD, University of Oklahoma; Int., Hospital of St. Raphael (Med/Surg); and Res., St. Francis Hospital, Hartford (Path), Henry Ford Hospital, Detroit (Derm). Interested in clinical dermatology and will consider a part-time position. Would also consider solo, group or associate type practice in a medium to large-sized community. Write, Lawrence J. Fortier, M.D., 1350 W. Bethune Ave., Apt. 509, Detroit, MI 48202.

FAMILY PRACTICE

July '85. Age 28. Nat'l bds. AB elig. MD, Upstate Medical Center, SUNY, Syracuse, NY; Int. and Res., University of Maryland Hospital. Prefers group or HMO type practice in a medium to large-sized community. Write, CSMS, c/o SL/FP.

INTERNAL MEDICINE

July '85. Age 29. FLEX. AB elig. MD, Indiana University School of Medicine; Int. and Res., University of Cincinnati. Prefers small to medium-sized community group or associate type practice in a small to medium-sized community. Write, Douglas J. Trigg, M.D., 515 Howell Ave., Cincinnati, OH 45220.

Sept. '85. Age 28. Nat'l bds. AB elig. MD, University of Washington; Int. and Res., Kaiser Foundation Hospital, San Francisco, CA. Prefers group, associate or institutional type practice in a medium to large-sized community (western Connecticut). Write, Susan K. Elgee, M.D., 85 Kent Court, #12, Daly City, CA 94015.

July '85. Presently in practice. Age 29. Nat'l bds. AB cert. MD, Downstate Medical School; Int. and Res., Brookdale Hospital, Brooklyn, NY. Prefers group, associate, institutional and industrial type practice within commuting distance of Stamford. Write, Catherine Cohen-Troy, M.D., 435 E. 79th St., Apt. 12-B, New York, NY 10021.

PULMONARY. July '85. Age 31. FLEX. AB cert. (IM). MD, Mahatma Gandi Memorial Medical College, Indore, India; Int. and Res., St. Clare's Hospital, New York, NY and Jamaica Hospital, New York, NY; Fellowship, St. Vincent's Hospital, Worcester, MA. Prefers solo, group or associate type practice in a medium-sized community. Write, Surendra K. Nevatia, M.D., 21 Heywood St., #2E, Worcester, MA 01604.

GASTROENTEROLOGY. July '85. Age 33. FLEX. AB cert. M.B.B.S., Baroda Medical College, M.S. University, Baroda, India; Int., Res. and Fellowship, Bronx-Lebanon Hospital, Bronx, NY. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Pravin N. Patel, M.D., 15 St. Andrew's Pl., #2J, Yonkers, NY 10705.

GASTROENTEROLOGY. July '85. Licensed in Connecticut. Age 33. FLEX. AB cert. (IM); AB elig. (GI). MD, Peruvian University Cayetano Haredia, Lima, Peru; Int. and Res., St. Vincent's Medical Center, Bridgeport, CT; Fellowship, St. Vincent's Medical Center (Yale affiliated GI program). Wishes group or associate type practice. Write, Hector R. Pun, M.D., 55 Fifth Ave., Stratford, CT 06497.

GASTROENTEROLOGY. July '85. Age 30. FLEX. AB cert. MD, Dublin University, Trinity College; Int., Sir Patrick Dun's Hospital; Res., Federated Dublin Hospitals and University of Nebraska Medical Center; Fellowship, Medical College of Virginia. Prefers group, associate or institutional type practice in medium to large-sized community near a medical school. Write, Michael N. Eppel, M.D., P.O. Box 8843, Richmond, VA 23225.

NEUROLOGY

Immediately available. Presently in practice. Age 36. FLEX. AB cert. (IM); AB elig. (NEUR). MD, University Bologna; Int. and Res., Nassau Hospital, Mineola, NY; Fellowship, University of Miami, Miami, FL. Prefers solo, group or associate type practice. Write, CSMS, JCMC/NEUR.

OBSTETRICS & GYNECOLOGY

July '85. Age. 26. Nat'l bds. AB cert. MD, Hahnemann University, Philadelphia, PA; Int., St. Raphael's Hospital, New Haven, CT; Res., Danbury Hospital, Danbury, CT. Seeking to join a group or associate type practice. Write, Les A. Burns, M.D., 6 Essex Court, Brookfield, CT 06804.

OPHTHALMOLOGY

Immediately available. Presently in practice. Age 31. Nat'l bds. AB elig. MD, Tufts University, Boston, MA; Int., Faulkner Hospital, Boston; Res., Bascom Palmer Eye Institute, Miami, FL; Fellowship, Katzen Eye Group, Mercy Hospital, Baltimore, MD. Prefers solo, group, associate, institutional or hospital based type of practice in a medium to large-size community. Write, P.O. Box 23656, Baltimore, MD 21203.

PHYSICAL MEDICINE AND REHABILITATION

Feb. '85. FLEX. AB elig. M.B.B.S., Shah Medical College, Jamnagar, India; Int., Lions Hospital, Bhavnagar, India; Res., Nassau County Medical Center, East Meadow, NY (Pathology) and University of Medicine & Dentistry of New Jersey (Rehabilitation Medicine) and V.A. Medical Center, Brooklyn, NY. Prefers solo, group or institutional type practice. Write, Minaxi K. Vora, M.D., 41 E. White Terrace, Nutley, NJ 07110.

RADIOLOGY

July '85. Age 41. FLEX. AB elig. MD and Int., Kasthurba Medical College, India; Res., NY Medical College, NY; Fellowship, St. Louis City Hospital, St. Louis, MO. Prefers solo, group, associate or institutional type practice. Write, A.S. Sidharthan, M.D., 6979 Blue Water Trail, St. Louis, MO 63123.

July '85. Age 30. Presently in practice. Nat'l bds. AB elig. MD, SUNY Downstate, Brooklyn, NY; Res., Long Island College Hospital, Brooklyn, NY; Int., Nassau County Medical Center, NY; Fellowship, St. Louis University Medical Center, St. Louis, MO. Prefers general X-Ray with emphasis on CT/Ultrasound with a group, associate, institutional or industrial practice in a large-sized community. Write, Richard S. Steinberg, M.D., 3701 Lindell Blvd., Apt. 427, St. Louis, MO 63108.

SURGERY

March '85. Presently in practice. Age 32. Nat'l bds. AB elig. MD, University of California, San Francisco School of Medicine; Int. and Res., University of California, San Francisco-Central San Joaquin Medical Education Program. Prefers multi-specialty group in a medium to large-sized community. Write, Eric E. Jones, M.D., P.O. Box 23656, Baltimore, MD 21207.

Dec. '84. Age 31. Nat'l bds. AB elig. MD, NY Medical College, Valhalla, NY; Int., Res. and Fellowship, St. Vincent's Hospital and Medical Center of New York, NY, NY. Prefers group or associate type practice. Write, Nicholas G. Bonvicino, M.D., 130 West 12th St., Apt. 5-J, New York, NY 10011.

July '85. Age 33. Presently in practice. FLEX. MD, University of The West Indies, University Hospital of The West Indies; Int., Res. and Fellowship, Harlem Hospital Center (affiliated with Physician & Surgeons, Columbia). Prefers group, solo, or associate type practice in that order. Write, Derrick J. Martin, M.D., 13-2 Granada Crescent, White Plains, NY 10603.

July '85. Age 29. Nat'l bds. AB elig. MD, Trinity College, Dublin, Ireland; Int., Sir Patrick Duns Hospital, Ireland; Res., Washington Hospital Center, Washington, DC. Will consider any type practice. Write, Karl W. Sorenson, M.D., 6724 Conway Ave., Takoma Park, MD 20912.

July '85. Age 34. FLEX. AB elig. MD, Maulana Azad, University of Delhi, India; Int., Irwin and G.B. Pant Hospitals, New Delhi; Res., Youngstown Hospital Assoc., Youngstown, OH and Robert Packer Hospital, Sayre, PA. Prefers solo, group or associate type practice. Write, Naresh C. Nagpal, M.D., 323 A Hyaden St., Syre, PA 18840.

UROLOGY

July '85. Age 32. MD, Hospital of India; Res., Brookdale Hospital, NY; Res., University of Minnesota. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Binod Sinha, M.D., 3425 Golf View Dr., Eagan, MN 55123.

FOUNDED IN 1792

The Connecticut State Medical Society

SUMMARY OF CSMS
HOUSE OF DELEGATES–ANNUAL MEETING
May 8, 1985

Reports and Addresses

The House received reports, addresses and/or remarks from the President, Secretary, Treasurer, the Council, Delegates to AMA, Chairman of the Board of Directors of COMPAC, the Executive Director, the President of the Auxiliary to CSMS, Standing Committees, Representatives and Advisors, and the delegates from New Jersey, Vermont, and Rhode Island.

Election of Officers and Others

The House voted to approve the published report of the Nominating Committee (the Council) with minor amendments. Officers elected were:

President: William A. Whalen, Jr., M.D., Willimantic
President-Elect: Joseph C. Czarsty, M.D., Oakville
Vice-President: James P. Orphanos, M.D., Greenwich
Secretary: Norman A. Zlotsky, M.D., Rockville
Treasurer: Robert R. McDonnell, M.D., New Haven
Speaker of the House of Delegates:
Lawrence B. Ahrens, M.D., Wethersfield
Vice-Speaker of the House of Delegates:
Mehdi S. Eslami, M.D., Waterbury

One Delegate and one Alternate Delegate to the AMA for the term January, 1986 to December 31, 1987 (Terms of other delegates do not expire until December 1986)

Edward A. Kamens, M.D., Fairfield (D) 1/1/86-12/31/87
Isadore H. Friedberg, M.D., Newington (A) 1/1/86-12/31/87

Councilor-at-Large:
Joseph S. Sadowski, M.D., Hartford

Commendation

It was unanimously VOTED to commend John C. Mendillo, M.D., New Haven, retiring Treasurer, for his many years of dedicated service to the Society.

Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House of Delegates were heard by reference committees and based on the reports of the reference committees were acted on as follows:

Committee Membership

VOTED to increase the membership strength of two committees as follows:

Committee on Legislation–20 to 24
Medical Aspects of Sports–20 to 24

Bylaw Amendments

VOTED to approve the following amendments to the CSMS Bylaws:

Article XII, Section 4, Par. 1

Delinquency: Change the date of dues delinquency from August 1 to April 30.

Article VI, Section 8

Duties of the President: Add to the duties of the president, that he shall serve as an additional alternate delegate to the AMA.

Unified Membership

VOTED to approve the following substitute resolution:

RESOLVED, That the Council of the Connecticut State Medical Society be directed to establish, in cooperation with constituent county associations and the American Medical Association, a program to promote the concept of unified membership and to increase awareness of the membership of the benefits and importance of belonging to their respective county medical associations, the Connecticut State Medical Society and the American Medical Association toward the end that unified membership be accomplished; and be it further

RESOLVED, That the Council report its activity in this area to the House of Delegates at its 1985 interim meeting.

Conflict of Interest Guidelines

VOTED to approve, with minor amendments, the Conflict of Interest Guidelines as developed by the AMA Judicial Council, which follow:

a. The physician has an ethical obligation to disclose to the patient or referring colleagues, his or her ownership interest in a recommended facility or therapy prior to utilization.

b. The physician may not exploit the patient in any way–as by inappropriate or unnecessary utilization.

c. The physician's activities must be in strict conformance with the law.

d. The patient should have free choice either to use the physician's proprietory facility or therapy or to seek the needed medical services elsewhere.

e. When a physician's commercial interests conflict so greatly with the patient's interest as to be incompatible, the physician should make alternative arrangements for the care of his patient.

Vaccine Compensation

VOTED to approve the following resolution:

RESOLVED, That the Connecticut State Medical Society supports the drafting of federal legislation, as developed by the American Medical Association and appropriate specialty societies, for the appropriate compensation of persons seriously injured as a result of mandated or recommended immunizations; and be it further

RESOLVED, That the Connecticut State Medical Society inform the members of the Connecticut congressional delegation as to the seriousness of this problem, and urge them to act quickly on an appropriate legislative proposal so that the epidemics of preventable diseases we have suffered in previous years may be avoided, and that non-negligent physicians and pharmaceutical companies may be protected from liability.

Smokeless Tobacco

VOTED to approve the following resolution:

RESOLVED, That the Connecticut State Medical Society declare that snuff dipping and tobacco chewing are hazardous to one's health, and are certainly not safe alternatives to smoking; and be it further

RESOLVED, That the Connecticut State Medical Society urge physicians in Connecticut to make every effort to discourage the use of smokeless tobacco; and be it further

RESOLVED, That a copy of this resolution be directed to the Surgeon General of the United States urging him to require a health hazard warning on smokeless tobacco similar to the warning currently on cigarettes; and be it further

RESOLVED, That a copy of this resolution be directed to the Chairman of the Federal Trade Commission urging him to initiate a rulemaking proceeding under Section 18 of the Federal Trade Commission Act to require manufacturers of smokeless tobacco to warn consumers of the link between the use of these products and oral cancer; and be it further

RESOLVED, That a copy of this resolution be directed to the Connecticut Dental Association, Connecticut Heart Association, American Lung Association of Connecticut, the Connecticut Division of the American Cancer Society and to the American Academy of Otolaryngology and Head and Neck Surgery.

Appointment of a Professional Advisory Committee

(Public Act 84-315)

Public Act 84-315 has established a prospective payment system (PPS) for hospitals, commencing in 1985, and also provides for the establishment of an advisory committee for the purpose of addressing such issues as changes in technology, clinical practice patterns and other changes affecting the delivery of hospital and medical care. The committee is to be appointed by the Governor with two physicians serving as representatives of CSMS. The House of Delegates took the following action:

VOTED to approve the following resolution:

RESOLVED, That the Council of the Connecticut State Medical Society elect two physicians as nominees to serve on the Professional Advisory Committee; and be it further

RESOLVED, That the names of the two CSMS nominees be submitted to the Governor and that the Governor be strongly urged to immediately appoint the Professional Advisory Committee and initiate its vital activities.

Presentations and Awards

AMA-ERF Grants to Medical Schools: Provided by the AMA Education and Research Foundation, grants were awarded as follows: To the Yale University School of Medicine—$6,874.08. Accepting for Yale was Howard Levitin, M.D., Dean of Students. To the University of Connecticut School of Medicine—$4,556.50. Accepting for UConn was Milton Markowitz, M.D., Associate Dean of Student Affairs.

Connecticut Health Science Fair Awards: For the first time, CSMS participated in the Connecticut Health Science Fair and established CSMS awards for academic excellence for students in grades 7-12, who participated in the annual fair. First prize winner, senior division was Elizabeth Rees of Norwalk, a student at Brian McMahon High School, for her project showing how mechanical prosthesis simulate human walking. First prize, junior division, went to Darren Tishler, Somers, a student at Somers Junior High School, for his project on "Computers and Science." Each winner received a plaque and a check for $200.

Presentation to Retiring President: In recognition of his efforts as President of the Society during 1984-1985, Joseph S. Sadowski, M.D., Hartford, was presented with a inscribed silver bowl and a past president's pin.

Presentation to Incoming President: Following his inauguration, a plaque with a gavel, symbolic of the office of President of the Society, was presented to William A. Whalen, Jr., M.D., Willimantic, by the retiring President, Joseph S. Sadowski, M.D. Following the presentation, Dr. Whalen gave his inaugural address, which placed emphasis on better communications between physicians and their patients, the intervention of the government into the practice of medicine, and the maintenance of quality of care at all times.

1985 CSMS ANNUAL MEETING HIGHLIGHTS

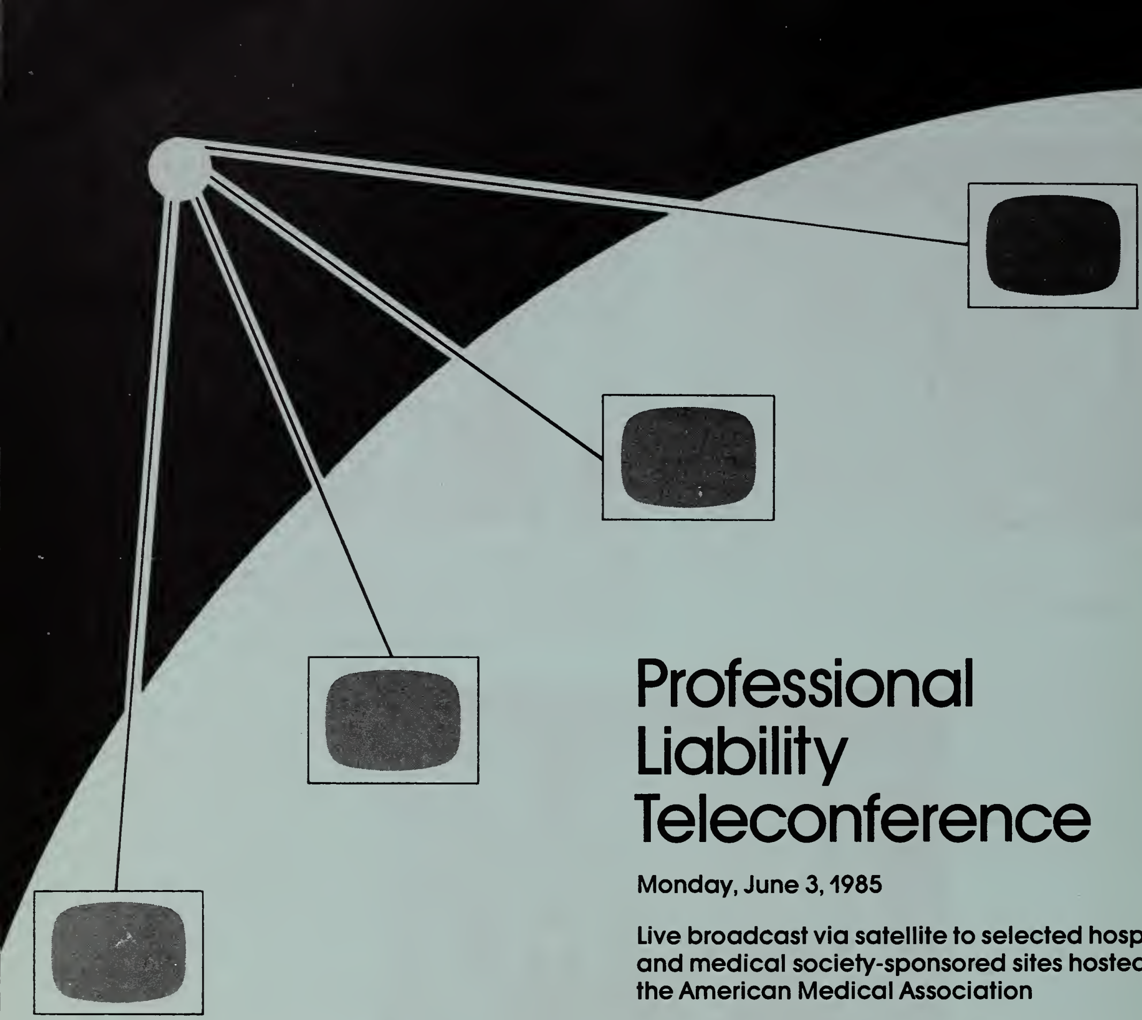
Joseph S. Sadowski, M.D., of Hartford, right, accepts a Past President's pin from Guy W. Van Syckle, M.D., of Danbury, Chairman of the Council, during ceremonies at the meeting.

William A. Whalen, Jr., M.D., of Willimantic, newly installed President of the Society, addresses his inaugural comments to the House of Delegates during the 193rd Annual Meeting held May 8, 1985 at the Park Plaza Hotel, New Haven. Dr. Whalen is the 148th President of the Connecticut State Medical Society.

Dr. Joseph Sadowski, President CSMS, and Mrs. Bobbi Czarsty, Auxiliary Chairperson of the AMA-ERF, present AMA-ERF checks to aid needy medical students to: Howard Levitin, M.D., Dean of Students, Yale University School of Medicine, and Milton Markowitz, M.D., Associate Dean of Student Affairs, University of Connecticut School of Medicine.

Elizabeth Rees, left, of Norwalk, and Darren Tishler, of Somers, received inscribed plaques at the House of Delegates meeting. The awards were presented to the students as first prize winners in the Senior and Junior Divisions of the CSMS Awards for Academic Excellence, for students in grades 7-12 who participate in the Annual Connecticut Science Fair.

Mrs. Marilyn Eslami, President of the Auxiliary to the Connecticut State Medical Society, presents her year-end report to the CSMS House of Delegates.



Professional Liability Teleconference

Monday, June 3, 1985

Live broadcast via satellite to selected hospitals and medical society-sponsored sites hosted by the American Medical Association

Produced by Hospital Satellite Network

Monday, June 3, 1985
A 2-hour program
beginning:

1:00 pm	Eastern
12:00 noon	Central
11:00 am	Mountain
10:00 am	Pacific

The AMA will host a comprehensive review of today's professional liability problem and describe a national program to address it. Experts in medicine, law and insurance will discuss what is being done now to bring about a solution.

Learn what the AMA is doing to combat the problem, including . . . what federal legislation the AMA proposes . . . how some states have successfully enacted tort reform . . . and what kinds of risk management programs are effective.

You will be able to phone in questions to the experts during this live telecast.

Contact your state medical association to find out where in your area you may view the program, or call toll free 1-800-638-3336. In California, call 1-800-624-5860.

Category 1 CME credit is available.

AMA
AMERICAN MEDICAL ASSOCIATION

The Use of Adjuvant Chemotherapy for Breast Cancer in a Community Practice

ARTHUR ROSENBERG, M.D., ERIC P. WINER, M.D. AND ED CADMAN, M.D.

ABSTRACT—Sixty-five women following a mastectomy for breast cancer were given adjuvant chemotherapy in a non-university office practice. Treatment consisted of cyclophosphamide 50-100 mg po daily, methotrexate 2.5 mg po tid for three days each month, vincristine 2 mg IV each month, 5-fluorouracil 500-1000 mg IV weekly, and prednisone 15-20 mg po daily for six months. Treatment was continued for one year. Twenty patients (31%) have relapsed and 11 patients (17%) have died. The median follow-up is 50 months. Eighteen percent of premenopausal women (5/28) relapsed while 41% (15/37) of postmenopausal women relapsed (not significant). Of the 16 premenopausal patients with 1-3 positive nodes, only one patient relapsed (6%) compared to eight relapses in the 22 postmenopausal patients who had 1-3 nodes which contained tumor ($p < 0.05$). The relapses in those patients with more than four positive nodes were: premenopausal 33% (4/12), postmenopausal 47% (7/15). These results are comparable with the best reported in the literature, and indicate that successful adjuvant chemotherapy can be given to the average woman with breast cancer cared for by a local oncologist in the community.

Introduction

Adjuvant therapy for breast cancer patients who are at high risk for tumor recurrence has become rather common. Multiple recent clinical studies have demonstrated some benefit, especially to those women who are premenopausal with axillary nodes which contain tumor.[2-5,7-9,11] Although cyclophosphamide, methotrexate and 5-fluorouracil (CMF) have received perhaps the greatest amount of publicity, [2-5] other combination therapy has been found to be superior in some smaller clinical trials. The addition of vincristine and prednisone (CMFVP) may be more effective in postmenopausal women than CMF; however, the studies are of too short a duration to be absolutely certain,[11,13] with the exception of Cooper's program, which was initiated in 1968.[6] In 1975, the Cancer and Leukemia Group B initiated a comparative trial between CMFVP and CMP which demonstrated that CMFVP was perhaps superior to CMF in the postmenopausal women.[13] Adriamycin has also been used in combination with cyclophosphamide for the adjuvant treatment of women with breast cancer.[1,10,12] Since the majority of adjuvant studies have demonstrated some benefit to patients, this form of therapy has become common practice in the community. However, all published studies of adjuvant chemotherapy have been performed in the academic environment. The real impact of adjuvant therapy will only exist if these results can be duplicated by community oncologists. The following is a report of 73 women treated by one oncologist (AR) whose practice is located in a small community.

Patients and Methods

Seventy-three consecutive women who were considered high risk for recurrence of breast cancer following primary surgical therapy were given adjuvant chemotherapy. There were 32 premenopausal and 41 postmenopausal women. Six women (3 pre- and 3 postmenopausal) had no axillary node metastases. Forty patients (17 pre- and 23 postmenopausal) had one to three nodes with tumor, and 27 patients (12 pre- and 15 postmenopausal) had four or more nodes with tumor. No patient had inflammatory carcinoma or satellite skin lesions. Estrogen receptor assays were available from 61 patients. Modified radical mastectomies and axillary

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ARTHUR H. ROSENBERG, M.D., Attending Physician, Greenwich Hospital, Greenwich, CT; Associate Attending Physician, United Hospital, Port Chester, NY; Assistant Clinical Professor of Medicine, Department of Medicine, Yale University School of Medicine. ERIC P. WINER, M.D., Medical Resident, Department of Medicine, Yale University School of Medicine, New Haven, CT. ED CADMAN, M.D., Director, Cancer Research Institute, University of San Francisco, San Francisco, CA.

Reprint requests to: 42 Sherwood Place, Greenwich, CT (Dr. Rosenberg).

Supported in part by grant CA-08341 from the National Cancer Institute. Dr. Cadman is a recipient of a Faculty Research Award from the American Cancer Society.

dissection with node sampling were performed on all patients.

Two to three weeks after surgery, all patients were started on the following drug program: 1) cyclophosphamide 50-100 mg/po daily, 2) methotrexate 2.5 mg po tid for 3 days each month, 3) vincristine 2 mg IV each month, 4) 5-fluorouracil 500-1000 mg IV weekly, and 5) prednisone 15-20 mg po daily for six months. In patients considered a very high risk for recurrence (more than four nodes containing tumor), Adriamycin 70 mg IV was given every two months alternating with the methotrexate and vincristine. Treatment was adjusted to keep the white blood count near 4000/mm3 and platelet count between 125-150,000/mm3 and continued for one year.

The initial evaluation included routine blood tests, bone scan, liver-spleen scan, and chest x-ray. These tests were repeated after completion of therapy. During the first two years, the patients were seen at three-month intervals; after two years, the physician visits were at four-month intervals and extended to six-month intervals beyond three years.

Of the 73 patients originally treated, eight have not been included in the data analysis. The six patients without axillary node involvement, all of whom are free of cancer, have been excluded because their excellent prognosis would bias the overall results in a favorable fashion. Two other patients transferred their care to Greenwich from the Yale Comprehensive Cancer Center where they had been treated on a standard CMF program.

Results

The 65 patients who are included in the data analysis have been followed for a median of 50 months (range 23 to 95 months) as of January 31, 1983. The recurrence rates and disease-free survival have been calculated for the entire group as well as for various subgroups (Table 1 and Figures 1,2). Within the entire group, 20 patients (30.8%) have relapsed and 11 patients (16.9%) have died of progressive disease. The median time from diagnosis

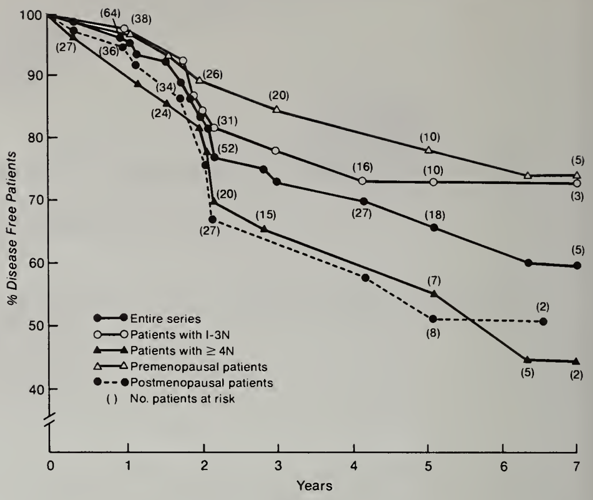

Figure 1

Disease-free survival of women with breast cancer treated with adjuvant chemotherapy. The number in parentheses represents patients.

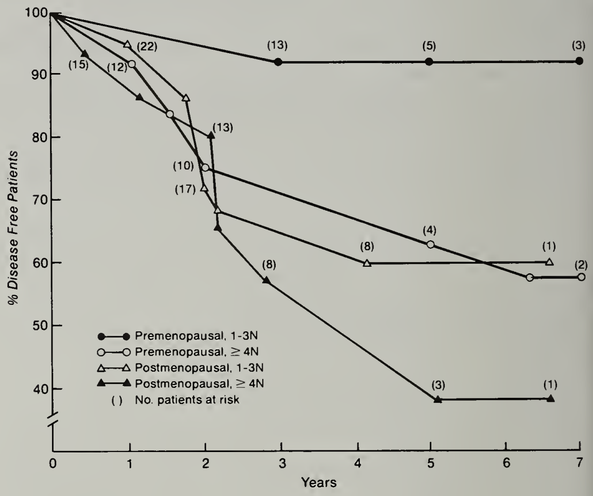

Figure 2

Disease-free survival of women with breast cancer treated with adjuvant chemotherapy. Patients are segregated into pre- and postmenopausal groups and nodal status.

Table 1

RECURRENCE PATTERNS AND FIVE-YEAR DISEASE-FREE SURVIVAL

Group of Patients	*Number Evaluable*	*Number Relapsed*	*Relapse Rate (%)*	*Five-Year Disease-Free Survival (%)*
Entire series	65	20	30.8	66
Premenopausal	28	5	17.9	85
Postmenopausal	37	15	40.5	51
1-3 Nodes	38	9	23.7	73
≥4 Nodes	27	11	40.7	56
Premenopausal, 1-3 Nodes	16	1	6.2	92
kPremenopausla, ≥4 Nodes	12	4	33.3	75
Postmenopausal, 1-3 Nodes	22	8	36.4	60
Postmenopausal, ≥4 Nodes	15	7	46.7	38

to recurrence among these 20 patients was 23 months (range 4 to 75 months). Fifteen of these patients (75%) relapsed within 25 months of diagnosis and 17 (85%) had relapsed within the first three years of follow-up. The remaining three patients had recurrences at 49, 60 and 75 months, respectively.

When divided according to nodal status, patients with minimal axillary involvement had a lower relapse rate than those with more extensive tumor dissemination. Among patients with one to three positive nodes, there were 9/38 (23.7%) recurrences as opposed to 11/27 (40.7%) for the group with ≥ 4 positive nodes ($p < 0.40$). Pre-menopausal patients had an advantage over those who were postmenopausal with relapse rates of 5/28 (17.9%) and 15/37 (40.5%) respectively ($p < 0.20$). If patients are subgrouped according to nodal and menstrual status, both factors appear to exert independent effects on recurrence rates. The most striking results were observed in the group of premenopausal patients with one to three positive nodes in whom there was only one relapse in 16 patients (6.25%); in postmenopausal patients with one to three nodes, there were 8/22 (36.4%) relapses ($p < 0.05$). In premenopausal patients with ≥ 4 nodes, there were 4/12 (33.3%) recurrences. Post-menopausal patients with ≥ 4 nodes had the highest rate of treatment failure with 7/15 (46.7) relapses. Nodal status appears to have had a greater influence on the recurrence rates of premenopausal than of postmenopausal patients.

The overall survival for the entire group is 83.1% and the six-year survival calculated on the basis of life table analysis is 74%. In premenopausal patients, there have been 3/28 (10.7%) deaths compared to 8/37 (21.6%) in postmenopausal women. In patients with 1-3 positive nodes, there have been 5/38 (13.2%) deaths as opposed to 6/27 (22.2%)in those with ≥ 4 positive nodes.

Estrogen receptor assays were available on 53 patients. Of these 53 patients, 29 (54.7%) had receptor-positive and 24 (45.3%) had receptor-negative tumors. Receptor-negative tumors were more common among premenopausal patients in whom 15/24 (62.5%) were negative, compared to 9/29 (31%) in postmenopausal patients ($p < 0.10$). There was no correlation between nodal status and receptor positivity/negativity either in the group as a whole or within the menopausal subgroups. When the group as a whole was analyzed, there appeared to be no relationship between relapse rates and receptor status. There were 10/29 (34.5%) relapses in receptor-positive patients and 8/24 (33.3%) in women whose tumors were estrogen receptor-negative. In the premenopausal subgroup, there were 2/7 (28.5%) recurrences in receptor-positive patients and 2/13 (15.4%) in receptor-negative patients. Among postmenopausal patients, the recurrence rate was 8/20 (40%) in women with receptor-positive tumors and 6/9 (66.7%) in those who were negative. Given the small number of patients, it is difficult to attach much importance to the slightly higher recurrence rates in premenopausal receptor-positive and postmenopausal receptor-negative patients.

Overall, the compliance was good and the toxicity of the regimen was fairly minimal. The side effects encountered were: 1) gastrointestinal—nausea, vomiting and diarrhea which were not severe; 2) easy fatiguability; 3) burning sensation in eyes; 4) weight gain which often persisted even after prednisone was discontinued; 5) sleep disturbances; 6) stomatitis; 7) alopecia (only in those patients receiving Adriamycin), and 8) mild neurological toxicity which resulted in the reduction of the subsequent dose of vincristine. No patients had a white blood count of less than 2000/mm3.

Discussion

Since all of the patients in this series received essentially the same drug regimen, we must rely on untreated historical controls and patients treated in other adjuvant programs to provide a basis for comparison. Given the heterogeneity of the patient population with breast cancer, this form of analysis is inexact and potentially misleading, particularly if we compare entire groups of patients without taking into account the variable clinical characteristics of the individual groups. If, on the other hand, we restrict our comparisons to subsets of patients with similar features (i.e., premenopausal patients with one to three positive nodes), it seems likely that we can increase the accuracy of our conclusions.

Before comparing our results to those reported in other series, several points need to be made concerning the recurrence patterns in this study. Perhaps the most important finding was that premenopausal women had a much lower recurrence rate (17.9%) than postmenopausal patients (40.5%). This difference is in large part due to the contribution made by the subset of 16 premenopausal patients with one to three positive axillary nodes. In this group of patients, the recurrence rate (6.25%) was far lower than in the corresponding group of postmenopausal patients (36.4%). When patients are divided according to nodal status, women with one to three nodes did better than those with ≥ 4 nodes (23.7% vs. 46.7%). Once again, however, the premenopausal subgroup with one to three nodes is primarily responsible for this margin. Although patients with ≥ 4 nodes had higher recurrence rates than those with one to three nodes regardless of menopausal status, the difference was more pronounced among premenopausal patients. In fact, when one examines the relapse patterns of the four subgroups, it becomes apparent that premenopausal patients with ≥ 4 nodes and both groups of postmenopausal patients had relatively similar rates of recurrence. In contrast, premenopausal patients with one to three nodes had a much lower rate of treatment failure than any of the groups individually or when they are grouped together.

The lower recurrence rates for premenopausal patients, and particularly those with minimal axillary involvement, does not appear to be due to a delay in recurrence in this subgroup compared to the others. The median follow-up for premenopausal patients who remain free of disease is 55 months compared to 46.5 months for postmenopausal patients. Of the 10 premenopausal patients who were diagnosed more than five years prior to this writing, eight are still free of disease (5 with 1-3 nodes and 3 with ≥4 nodes). Furthermore, the interval between mastectomy and relapse is no longer for premenopausal patients than for the group as a whole.

In comparing the recurrence rates of patients in this series to historical controls, it appears that both pre- and postmenopausal patients derived some benefit from the adjuvant regimen, but to widely varying degrees. Since the median time from the date of diagnosis is 50 months (range 24 to 95 months) in our series, we have chosen to compare our patients to controls at approximately four years from mastectomy. In the absence of adjuvant therapy, both pre- and postmenopausal patients have similar rates of treatment failure which is more closely related to nodal status than any other variable. At four years follow-up, most series report recurrence rates of 40-50% in patients with 1-3 positive nodes and 50-70% in patients with ≥4 nodes. By these standards, premenopausal patients in our series derived a clear-cut benefit from adjuvant therapy with relapse rates of 6.25% and 33% for the two nodal groups, respectively. Postmenopausal patients with one to three nodes appear to have a minimal reduction in recurrence rate (36.4%) in relation to the controls. The subgroup with ≥4 nodes appear to have had a somewhat more substantial reduction in treatment failure (46.7%) compared to the corresponding control population. Given the relatively small number of patients in this series and the equivocal results, it is difficult to draw any definite conclusions concerning the value of this adjuvant protocol in postmenopausal patients.

Our subgroup of premenopausal patients with one to three nodes did as well or better than any reported in the literature (Figure 3). Our results with this subset of patients are comparable to those reported in the Milan CMF trial after a 36-month follow-up and the SWOG trial of CMFVP after a 42-month follow-up.(3,11) While single-agent chemotherapy with L-PAM has been shown to be of some benefit in decreasing recurrences in this subgroup, the results have not been as impressive.[7,9] The combination of Adriamycin (A) and cyclophosphamide (C) has also been found to be effective, but with higher recurrence rates than in the CMF and CMFVP trials.[1] Our results with the subgroup of premenopausal patients with ≥4 positive nodes are also comparable to those reported in several adjuvant trials. Recurrence rates for this subgroup of patients in the Milan CMF, SWOG CMFVP, and Arizona AC series all range from 33% to 43%.[1,3,11] Even lower rates of treatment failure have been reported in Cooper's CMFVP trial (17%) and in the CMFVP arm of the Leukemia Group B series with a four-year actuarial disease-free survival of approximately 85%.[6,13] Both of these trials used regimens similar to our own. Thus, while we might have hoped for a lower recurrence rate in this subgroup of patients, it does appear that they derived a benefit from adjuvant therapy. Given the limited number of patients of this series, we can only conclude that our adjuvant regimen reduced the relapse rate in all premenopausal patients to a similar extent as seen in the more successful adjuvant trials that have been reported in the literature.

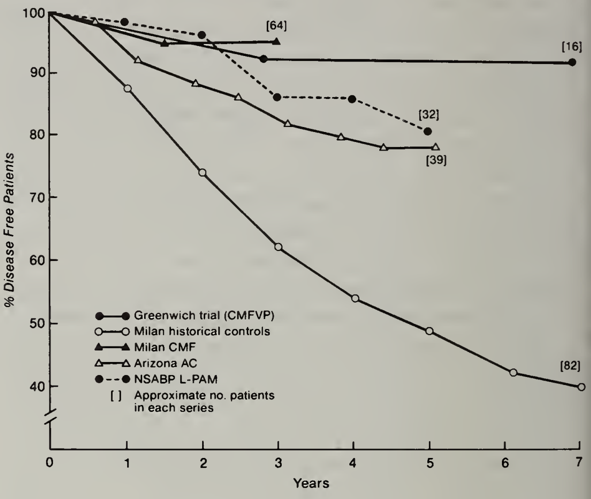

Figure 3

Disease-free survival of women with breast cancer treated with various adjuvant chemotherapy programs.

Our results with postmenopausal patients are remarkably similar to those achieved in the Milan CMF trial, with a 32% relapse rate in patients with one to three nodes and 44.3% in patients with ≥4 nodes after three years of follow-up. While patients in both nodal subgroups had lower rates of treatment failure than the controls, the differences were not statistically significant.[3] In contrast, using a CMFVP regimen, the SWOG reported recurrence rates of only 11% in patients with one to three nodes and 40% in women with ≥4 nodes after a median follow-up of 42 months.[11] In the Arizona AC trial, no difference was found between pre- and postmenopausal patients, with recurrence rates of 21% in patients with one to three nodes and 43% in those with ≥4 nodes.[1] While both the SWOG and Arizona trials yielded superior results in postmenopausal patients with minimal axillary disease, their findings in patients with ≥4 nodes were comparable to the data from Milan and from our own trial. As was the case with premenopausal patients, some of the lowest recurrence rates in postmenopausal patients with ≥4 nodes have been reported by Cooper and by the Leukemia Group B trial with 19% and 22% relapses, respectively. CMFVP was utilized in both, but unlike many other protocols, chemotherapy was initiated with a 6- to 8-week intensive induction phase. Thus, while our results with postmenopausal patients are in line with many of the studies in the literature, they are nevertheless quite disappointing.

Despite these problems, we are able to draw several conclusions from our results. A median follow-up of 47 months in those who are still disease-free allows us to be hopeful that recurrence rates are not going to change dramatically in our patients. This belief has already been partially confirmed by the analysis of the subgroup of patients diagnosed more than five years ago. The relapse rate (28.5%) in this subgroup is actually lower than in the entire group of patients. On the basis of our results, we can conclude that adjuvant CMFVP definitely appears to be effective in premenopausal patients, particularly in the group with minimal axillary involvement. In those with ≥4 nodes, CMFVP has altered the natural history of the disease, but there is still considerable room for improvement since one-third of these patients relapsed during our follow-up. In postmenopausal patients, our regimen has not been nearly as effective. While recurrence rates do appear to be lower than in historical controls, the difference is far less striking than in premenopausal patients. Since this regimen is certainly not free of toxic side effects, both physical and psychological, we must begin to question its routine use in postmenopausal women if it is only able to alter the outcome of such a small number of patients. More intensive regimens for both premenopausal patients with ≥4 nodes and all postmenopausal patients will have to be evaluated in future trials. An intensive induction phase and the administration of full doses in as many patients as possible may both prove to be effective in decreasing recurrences. In addition, studies will need to be conducted using two regimens that are not cross-resistant in a stepwise fashion. With further research, we may be able to identify markers which will help determine in a more exact manner which patients are in need of adjuvant therapy and how intensive the regimen will have to be for each individual.

While most of this work will have to be conducted at academic centers, our study provides direct evidence that effective treatment can be provided by a private practitioner working within a small community. The recurrence rates observed in our series are comparable to those achieved at most major centers. Only a small percentage of patients are seen by major centers and treated with rigorously defined protocols. The vast majority of patients are seen by physicians in their own communities. It is reassuring to see that adequate care in an area as complex as adjuvant chemotherapy can be provided in a variety of settings.

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Adverse Effects of Cyclophosphamide in Idiopathic Pulmonary Fibrosis

ORN ELIASSON, M.D., SOLON R. COLE, M.D., AND ARTHUR C. DEGRAFF, JR., M.D.

ABSTRACT—Eight patients with steroid resistant idiopathic pulmonary fibrosis (IPF) were treated with cyclophosphamide combined in most cases with prednisone. No response to cyclophosphamide therapy was observed as measured by clinical and pulmonary function parameters. Six patients experienced adverse effects possibly due to cyclophosphamide, including a probable cyclophosphamide-induced pulmonary fibrosis in one patient. While on cyclophosphamide two patients had unexplained dyspnea which recurred on challenge. Two patients developed a malignancy. Cyclophosphamide did not arrest the evolution of rapidly progressive pulmonary fibrosis. These results cast doubt on the usefulness of cyclophosphamide for the treatment of IPF, particularly in view of the serious adverse effects that can occur with its use.

Introduction

Idiopathic pulmonary fibrosis (IPF) represents a challenge to the pulmonary physician because of its variable response to treatment and its prognosis. Mean survival ranges from 47 to 55 months, but the disease can progress to death in weeks or remain stable for more than 20 years.[1-4] Corticosteroids have remained the mainstay of therapy, but an objective response is observed in only 20% of patients.[3] In the last decade clinicians have used immunosuppressive agents in IPF searching for improved response to therapy and prolongation of survival.[5-17] Immunosuppressive therapy has recently been recommended for steroid resistant cases.[18]

Our experience with immunosuppressors in IPF has been less than promising. The objective of this paper is to report eight patients with IPF in whom the administration of cyclophosphamide did not improve clinical status or pulmonary function but was instead associated with numerous adverse effects.

Materials and Methods

The pathology and pulmonary departments records of 28 patients (14 men and 14 women) with the diagnosis of pulmonary fibrosis, seen between 1970 and 1983, were reviewed retrospectively. Of the 22 patients who had adequately documented follow-up, only 2 (9%) demonstrated response to steroids as defined below. From these 22 cases were chosen all patients who had been treated with cyclophosphamide and who fulfilled the following criteria: Follow-up observation for at least 12 months or to death, available chest radiographs, physiologic tests and lung biopsy confirming the presence of pulmonary fibrosis. The chest radiograph had to show diffuse interstitial pattern. Physiologic test criteria were decreased lung volumes or decreased diffusion capacity. These patients showed either absence of response to or adverse effects of corticosteroids with or without rapid progression of disease.

All patients in whom an external fibrogenic agent could be implicated were excluded as were those who had pathologic evidence of granulomatous disease, particles indicating occupational disease or vasculitis. The criteria of Carrington and coauthors [1] were used in classifying the lung biopsies of the usual interstitial pneumonitis (UIP) and desquamative interstitial pneumonitis (DIP). The pulmonary pathology was reviewed and graded from 1 to 5 according to the same criteria. A diagnosis graded 1, 2, or 3 was considered a confident diagnosis of UIP or DIP.[1]

The onset of disease was defined as the time when dyspnea was first noticed. Response to therapy was defined as follows: Increase in FVC or VC by at least 10% of the predicted volume, maintained for at least a

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ORN ELIASSON, M.D., 2nd year Pulmonary Fellow, Division of Pulmonary Medicine, University of Connecticut Health Center. SOLON R. COLE, M.D., Assistant Professor of Pathology, University of Connecticut Health Center, Farmington; Associate Pathologist and Director, Electron Microscopy, Hartford Hospital. ARTHUR C. DEGRAFF, JR., M.D., Associate Professor of Clinical Medicine, University of Connecticut School of Medicine, Farmington; Director, Pulmonary Laboratory, Hartford Hospital, Hartford, CT.

Reprint requests to: Pulmonary Laboratory, Hartford Hospital, 80 Seymour St., Hartford, CT 06115 (Dr. DeGraff).

year and confirmed by parallel changes in TLC with or without simultaneous improvement in DLCO by 10% of its predicted value.

Results

Between 1970 and 1983 eight patients, five men and three women, who had been treated with cyclophosphamide, fulfilled the chosen criteria. All had at some time received prednisone; the average maintenance dose was 26 ± 13 mg (mean ± S.D.). The age at presentation was 62 ± 13 years. Before presentation subjective symptoms had been present for 1.6 ± .8 years and radiographic evidence had been present for 2.1 ± 1.8 years. The initial FVC, expressed as percent of predicted, was 60 ± 15 and the initial DLCO was 33 ± 10 percent.

As shown in Table 1, five patients had a confident histologic diagnosis of UIP, one had DIP grade 2-3 and two had UIP grade 5, or end-stage fibrocystic disease. Histologic evidence suggestive of rheumatoid lung disease was present in patient 4 who had rheumatoid arthritis with a positive rheumatoid factor (RF) and in patient 6 who had a positive serum antinuclear antigen but no clinical evidence of collagen vascular disease. Patient 5 also had a positive RF. The other patients had neither evidence of extrapulmonary disease nor serum autoantibodies. Patient 1 had a history of phlebitis and pulmonary embolism and was on anticoagulants. Patient 3 had mild congestive heart failure. Patient 4 had mild obstructive lung disease.

None of the patients responded with improvement on cyclophosphamide not even for a short period. On the contrary all the patients showed progressive deterioration while being treated, except patient 2 whose pulmonary function remained stable for seven years (Figure 1). Furthermore, six of the eight patients suffered adverse effects possibly attributable to cyclophosphamide and requiring discontinuation of therapy. A worrisome side-effect, increased dyspnea was observed in three patients:

Patient 1, a 48-year-old woman, who had remained stable on prednisone, developed unacceptable side-effects and was changed to cyclophosphamide while the prednisone was tapered and discontinued. On cyclophosphamide the patient soon became more dyspneic, while serial pulmonary function tests showed a rapid fall both in lung volumes and diffusion capacity.

Table 1

PATHOLOGY DIAGNOSIS AND GRADING AND CYCLOPHOSPHAMIDE DOSAGE

Patient	*Pathology Diagnosis and Grading*	*Maintenance Dose of Cyclophosphamide*	*Total Dose*	*Duration of Therapy*	*Survival*
1	UIP 2-3	100 mg	22 gm	5 months	8.5 years
2	UIP 2-3	50 mg	120 gm	5.5 years	9 years
3	UIP 1-2	100 mg	6 gm	2 months	46 months
4	UIP 1	50 mg	6 gm	4 months	
5	UIP 1-2	100 mg	4.4 gm	6 weeks	26 months
6	UIP 5	150 mg	5.8 gm	7 weeks	17 months
7	DIP 2-3	100 mg	4 gm	7 weeks	10 months
8	UIP 5	100 mg	4.2 gm	3 weeks	25 months

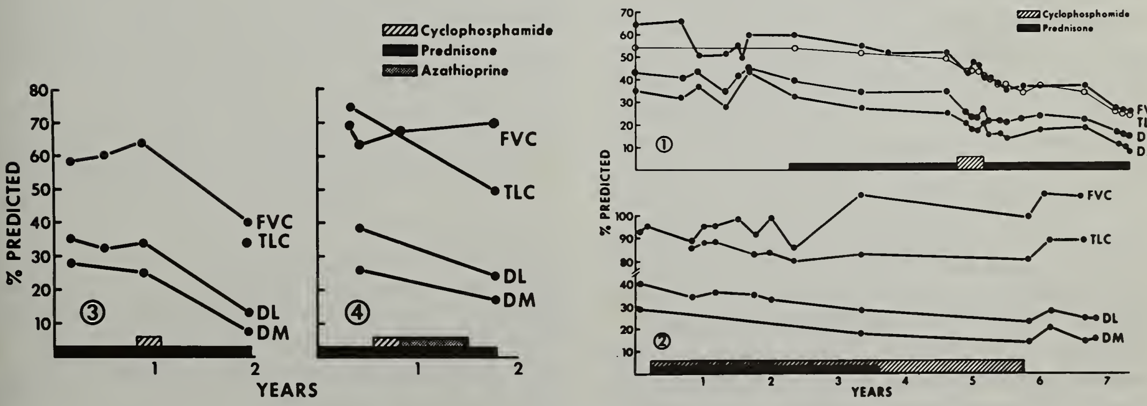

Figure 1

Serial pulmonary function in patients 1-4. The results are expressed as percent of predicted. FCV = forced vital capacity. TLC = total lung capacity. DL = carbon monoxide diffusion capacity. DM = membrane diffusion capacity.

During this period there was no clinical evidence of infection, no unusual environmental exposure and no other drug therapy. Cyclophosphamide was discontinued and prednisone 120 mg/day was begun with stabilization of pulmonary function (Figure 1).

Patient 3, a woman aged 79, who also had mild congestive heart failure, became increasingly dyspneic during a two month treatment with cyclophosphamide and required hospitalization. The dyspnea improved when the cyclophosphamide was discontinued. Because this latter improvement occurred in conjunction with oxygen and diuretic therapy, cyclophosphamide was reinstated alone, and after each dose there was a marked increase of respiratory symptoms which cleared when the cyclophosphamide was discontinued. Whereas the patient's pulmonary function had been stable previously, rapid deterioration followed the cyclophosphamide trial (Figure 1) and the patient died one year later of respiratory failure.

Patient 7, a 43-year-old man, noted worsening of dyspnea after a trial with cyclophosphamide. The patient, who was hospitalized and challenged with cyclophosphamide, experienced marked increase in dyspnea after each dose. Cyclophosphamide was discontinued and azathioprine begun, but the patient died of respiratory failure seven weeks after immunosuppressive therapy was initiated.

Other complications were as follows: Patient 4 developed hemorrhagic cystitis; the cyclophosphamide was replaced by azathioprine, but pulmonary function continued to worsen in spite of therapy (Figure 1). Patient 6 developed a fever and a skin rash while on cyclophosphamide and penicillin both of which were discontinued. When cyclophosphamide was reinstated, a high fever developed the next day and persisted after discontinuation of the drug. An infectious work-up including a repeat open-lung biopsy, which again showed UIP stage 5, did not reveal infectious agents.

Finally, two patients (1 and 2) developed neoplasia; one died of the complications of a perforated rectal carcinoma, and the other, who had received cyclophosphamide for several years, developed diffuse histiocytic lymphoma 18 months after discontinuation of therapy. These patients had received the highest cumulative dose of cyclophosphamide; 22 gms and 120 gms respectively.

Patients 5, 6, 7 and 8 had a rapidly fatal course. All four died of respiratory failure or related events less than two months after onset of cyclophosphamide therapy. The treatment did not appear to diminish in any way the progression of the disease. These patients had been symptomatic for a relatively short period and had worse pulmonary function on presentation than the other patients. Patient 7 survived only ten months after onset of dyspnea and probably qualifies as having had an accelerated variant of IPF.[2] Two of these patients (6 and 7) suffered adverse effects from cyclophosphamide.

Discussion

The rationale for immunosuppression treatment of IPF has been based on indirect evidence that the disease represents the pulmonary manifestations of a systemic immunologic illness.[19] In spite of recent recommendations to use immunosuppressive drugs in IPF when steroids fail,[18] there is little evidence that such an approach is beneficial. In fact the only randomized trial to date revealed that the combination of azathioprine and steroids was no better than steroids alone.[17]

Reviewing the literature we found 41 cases of IPF where the treatment had included cyclophosphamide.[2, 5-13] Sixty percent of the patients were deemed improved by the authors, who often used criteria for response of questionable validity such as subjective improvement of exercise tolerance and changes in the chest radiograph.[5, 14] Twenty-eight of these patients came from one institution [5, 8, 9] and while in the initial reports 15 of these were called responders, the author of a subsequent review article from the same institution could apply criteria of response, similar to ours, to only seven of the 28 patients, three of whom were now called responders.[6]

Similarly we found 40 reported cases of IPF, excluding the randomized trial, where azathioprine had been given.[5, 8, 9, 15] Fifty percent of these patients were considered improved. Meier-Sydow also described ten patients treated with azathioprine and steroids, who lived longer than expected with steroids only.[16] As in the cyclophosphamide reports, criteria for response varied considerably and based on sometimes insufficiently reported data only 12 of these patients[15] qualified as responders according to our criteria.

It is obvious that experience with immunosuppression in IPF has been scant and the evidence in its favor is anecdotal only. The unpredictable pattern of steroid responsiveness as well as the similarly unpredictable and intermittent progress of the disease are probable reasons why many authors find improvement with immunosuppressive therapy in uncontrolled trials. We also suspect that poor or negative results of this approach have been under-reported. In fact, if the success rate of cyclophosphamide therapy in IPF is sixty percent, as an optimistic reviewer of the literature might conclude, the probability of obtaining eight failures out of eight, as in our experience, is less than one in a thousand.

Cyclophosphamide is not an inoffensive drug. It has numerous and severe side effects which include pulmonary fibrosis and increased susceptibility to viral and bacterial infections.[20-24] We did not find any reports on adverse effects of cyclophosphamide in IPF. However, its use in this disease could theoretically cause additional fibrosis and turn relatively benign respiratory infections into lethal ones.

Three of our patients had increased dyspnea while on cyclophosphamide. Two of these patients lived long enough to have serial pulmonary function tests which in both cases showed rapid deterioration that coincided with the onset of cyclophosphamide therapy. In the case of patient 1 this process was halted by discontinuation of cyclophosphamide and the institution of high dose steroid therapy. It is a tantalizing thought that patient 1 may have had cyclophosphamide-induced pulmonary fibrosis. Steroids have been reported to have a protective effect in pulmonary fibrosis induced by cyclophosphamide[24] and it is interesting that this patient was tapered off steroids while receiving the immunosuppressor. Another explanation for this patient's symptoms and change in pulmonary function may have been an acceleration of the fibrotic process while off steroids. If so, the cyclophosphamide did not prevent such a relapse. There was no clinical evidence of infection during this period of deterioration. This patient had a history of pulmonary emboli but remained adequately anticoagulated and recurrent emboli would not cause a decrease in lung volumes as observed.

One of our patients developed rectal carcinoma and another patient developed lymphoma. Neoplasia in patients with IPF treated with immunosuppressive therapy has not been described previously but could be expected. In 1965 Meyer and Liebow described a relationship of interstitial pneumonia to cancer of the lung[25] and Turner-Warwick has recently reported that patients with IPF have an increased risk of lung cancer when compared to the general population.[26] Our patients who developed neoplastic disease had the longest survival and had received the highest doses of cyclophosphamide. Although the neoplasia may not have been related to the cyclophosphamide, the carcinogenic potential of immunosuppressive agents is well established.[27]

In conclusion we found no evidence that cyclophosphamide is effective in treating IPF. On the contrary, the rate of progression of the disease may be increased and the patients may be placed at increased risk of developing cancer. While it is possible that a subgroup of patients with IPF may benefit from immunosuppression, as suggested by Haslam and coauthors,[13] no such subgroup has been identified yet with any certainty. In view of the poor quality of the data that support the use of cyclophosphamide in IPF, and the present report of its adverse effects, although also of anecdotal nature, we suggest caution in using the drug until the results of a controlled evaluation are available.

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Optic Disc Edema Due to Iron Deficiency

Occurrence with Normal Cerebrospinal Fluid Pressure

HOWARD S. FORSTER, M.D.

Abstract—A man with optic disc edema was found to have iron deficiency anemia due to a bleeding gastric ulcer and gastritis. The edema resolved rapidly with iron therapy, and the anemia more gradually. He differed from most previously reported patients with this condition in having a normal cerebrospinal fluid pressure. There was no evidence of brain tumor. A metabolic disturbance localized to the papillae was considered to have been present.

Papilledema secondary to elevated cerebrospinal fluid pressure in the syndrome of benign intracranial hypertension, or pseudotumor cerebri, is a rare manifestation of iron deficiency anemia. Optic disc edema may also occur due to iron deficiency in the absence of intracranial hypertension, as in the following case. The recognition of the importance of iron in the pathogenesis and treatment of these conditions will reduce suspicions of brain tumor and simplify management.

Case Report

A 53-year-old man was admitted to The Meriden-Wallingford Hospital with the diagnosis of bilateral papilledema on 13 October 1983. Blurring of vision preceded the hospitalization for one month. The patient had retired from his job as a lacquer sprayer in 1980 on account of exertional dyspnea attributed to interstitial lung disease. He had bilateral pneumonitis in 1972 and smoked two to three packs of cigarettes per day.

This man was hospitalized with abdominal pain in 1973 due to antral and duodenal ulcers. There had been no documented recurrence of these although heartburn relieved by antacids was regularly experienced. He had drunk up to 12 cans of beer daily until 1981, but no alcohol since that time. Medications included diazepam, theophylline, and occasionally, aspirin.

Initial examination showed a nonobese white male in no distress, with normal vital signs except for a respiratory rate of 20 per minute. Refracted visual acuity was 20/20 O.D. and 20/25 O.S. The blindspots were enlarged and visual fields constricted peripherally. Both optic discs were swollen with engorged vessels and flame hemorrhages. Blood tests were as follows: hemoglobin, 10.7 gm/100ml; hematocrit, 33.5%; red blood count (rbc), 4.52 million/cu mm; mean corpuscular volume (mcv), 74 cu mm; white blood count (wbc), 8.4 thousand/cu mm; reticulocyte count, 1.7%; platelet count, 563 thousand/cu mm; erythrocyte sedimentation rate (esr), 64 mm/hr; chemistry profile, normal; serum ferritin (reported later), less than 10 ng/ml. The chest xray showed emphysema with prominent interstitial markings and the electrocardiogram, nonspecific ST-T wave changes and frequent premature ventricular contractions. A CT scan of the head with and without contrast was normal. Lumbar puncture after admission gave an opening pressure of 150 mmH$_2$0 with clear cerebrospinal fluid containing 33 mg/100ml protein and 60 mg/100ml glucose.

Treatment with 60 mg of prednisone and 525 mg of ferrous sulfate (Fero-Grad-500) per day was started on 13 and 14 October, respectively. Bone marrow obtained on the day after admission showed erythroid hyperplasia and absent iron stores. Occult blood was present in the stool. An upper gastrointestinal xray (UGI) demonstrated a small hiatal hernia and prominent prepyloric folds. After gastrointestinal panendoscopy revealed a prepyloric gastric ulcer and chronic gastritis, ranitidine and sucralfate were prescribed, the prednisone discontinued, and the iron preparation increased to twice daily.

A test for carboxyhemoglobin by a microdiffusion method on the seventh hospital day was markedly positive. The arterial blood gases on room air were as follows: $p0_2$,63 mmHg; $pC0_2$, 34 mmHg; calculated 0_2 saturation, 92.2%; pH, 7.45. The patient's cigarette smoking was stopped. The reticulocyte count had risen to 4.7% by 22 October. Prior to discharge 27 October, the hemoglobin was 10.7 gm/100ml, hematocrit, 34.1%, rbc, 4.39 million/cu mm, mcv, 79 cu mm, platelet count, 417 thousand/cu mm, and esr, 19 mm/hr.

The patient began to smoke a half pack of cigarettes per day after leaving the hospital. Ocular examination on 28 October showed resolving optic disc edema (Figure 1). Refracted visual acuity was 20/20 O.D. and 20/25 O.S. with visual fields that were minimally changed from preadmission (Figure 2). On 3 January 1984 the hemoglobin was 15.8 gm/100ml, hematocrit, 48.4%, rbc, 5.390 million/cu mm, and mcv, 90 cu mm. An UGI at that time redemonstrated the small hiatal hernia and mild gastritis. He has remained asymptomatic except for exertional dyspnea through July 1984.

Capriles reviewed the subject of intracranial hypertension and papilledema resulting from iron deficiency anemia in 1963, finding 29 adequately documented cases and adding four of his own; the cerebrospinal fluid pressures were elevated when they had been measured, and this was almost always accompanied by papilledema.[1] Subsequently, there have been seven additional reports in English language journals to 1983.[2-7] These more recent patients resembled the earlier ones in the severity of their anemia, their female preponderance, and recovery with iron therapy. They were, in general, diagnosed and treated at an earlier stage and irreversible visual consequences were avoided. Of these, only the two described by Trujillo et al. had normal cerebrospinal fluid

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HOWARD S. FORSTER, M.D., Private Practitioner, Internal Medicine, Meriden, CT; Attending Physician, The Meriden-Wallingford Hospital, Meriden, CT.

Reprint requests to: 377 Broad St., Meriden, CT 06450 (Dr. Forster).

pressures.[4] (One other, referred to in a 1971 text, had such a finding.[8]) One of these seven was discovered among series of patients with benign intracranial hypertension published over the past several years,[6] the majority having appeared as isolated case reports; unfortunately, as was stated in 1963 concerning reports of intracranial hypertension of unknown cause, "the authors appeared to pay little attention to the patients' blood picture."[1]

In most cases of pseudotumor cerebri, reduced cerebrospinal fluid absorption and secondary cerebral edema are believed to be present.[9] In this situation, papilledema results from transmission of pressure into the intravaginal space about the optic nerve, increased ophthalmic artery blood flow and peripapillary congestion in the capillary circulation.[10] Capriles emphasized the potential role of the depletion of iron-containing enzymes in the pathogenesis of the cerebral edema. Studies have shown that in severe iron deficiency there is a decrease in tissues of iron-containing heme proteins involved in oxidative metabolism as well as impairments in protein synthesis.[11] The probable importance of such a localized metabolic disturbance is underscored by the rapid resolution of the disc edema before the occurrence of a significant rise in the hemoglobin concentration. Additionally in this man, the elevated blood carboxyhemoglobin in the presence of a mild anemia may have produced an element of ischemic optic neuropathy by interfering with tissue oxygen delivery.

This patient, along with three previous ones, is unusual in that the spinal fluid pressure was normal and intracranial hypertension was presumably absent. In these, disordered metabolism localized to the papillae has to be postulated.

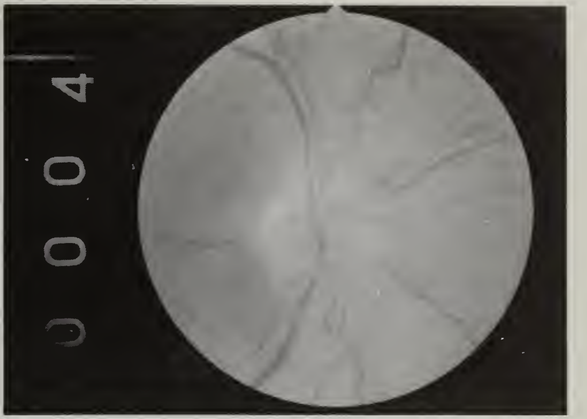

Figure 1A

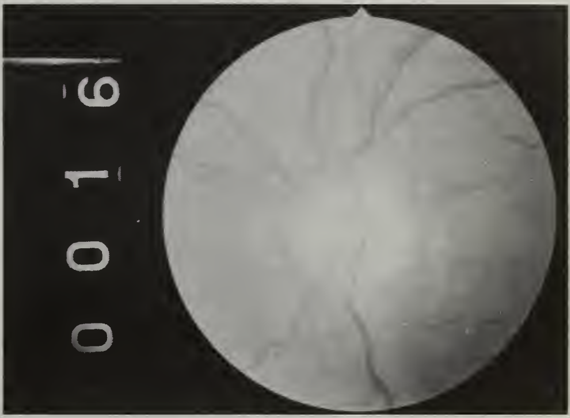

Figure 1B

Photographs of the ocular fundi on 28 October show resolving optic disc edema with blurred margins nasally, mildly engorged and tortuous veins, edema of the nerve fiber layers (especially of the left eye), and resorbing superficial hemorrhages. A. Right eye. B. Left eye.

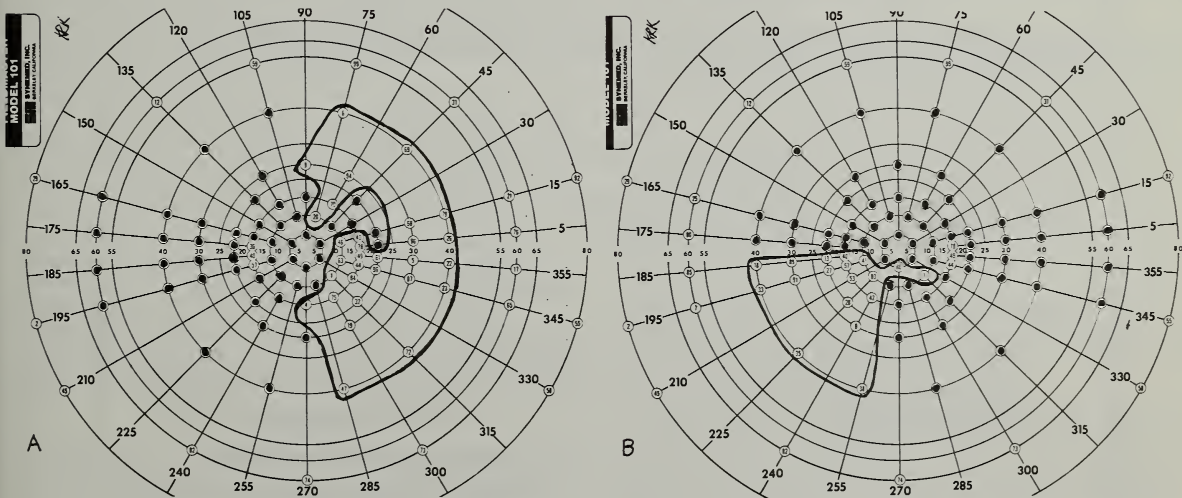

Figure 2A

Figure 2B

Visual field examinations on 28 October show an irregular nasal defect of the left eye (A), and an infero-nasal quadrantic defect of the right (B).

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Spontaneous Idiopathic Spermatic Cord Hematoma

MICHAEL S. GILLIGAN, M.D. AND SUBHASH O. SHAH, M.D., F.A.C.S.

ABSTRACT—Presented is an unusual case report of spontaneous idiopathic spermatic cord hematoma. It is noted in the literature that this condition usually occurs as a result of stressful exercise, with the preoperative diagnosis being incorrect. It has been confused with testicular torsion, incarcerated inguinal hernia and spermatic cord tumor.[1-4]

Patient and Method

A careful search of the English literature shows six previous reported cases of spontaneous idiopathic spermatic cord hematoma with two cases of spermatic cord hematoma secondary to blunt trauma.[5]

The following case report is described to add to the list of spontaneous idiopathic spermatic cord hematoma as a clinical entity.

Case Report

A 25-year-old male presented to the emergency room with a right groin mass. On admission, the patient stated to have noted a sudden tearing with pain in his right groin while lifting a box of tiles at work, three days prior to admission. The pain persisted and a mass developed which became progressively more tender.

On admission, the physical examination revealed a mass in the right groin, three centimeters in diameter, tender to palpation, firm, which did not transilluminate light. There was no history of blunt trauma, blood dyscrasia, inguinal hernia, urinary problems or anticoagulant treatment.

The admitting diagnosis was an incarcerated inguinal hernia and the patient was explored shortly after admission.

At operation, a mass was found, which appeared grossly as a hematoma, firm to palpation, which retracted easily in and out of the internal ring, in intimate contact with and arising from the pampiniform plexus of veins. The mass was excised in toto.

Pathology revealed a 6 x 1.5 x 1.0 cm mass covered by blood clot, with histology, showing numerous venous structures set in fibroadipose tissue, consistent with recent hematoma of the pampiniform plexus of veins.

Discussion

Although rare, spontaneous hematoma of the scrotum and spermatic cord has been described secondary to anticoagulant therapy,[8] with Henoch Schonlein Syndrome, and as a result of blunt trauma.[6]

It has been reported that spermatic cord veins normally have a supine pressure of 14 cm. of water and a standing pressure of 23 cm. of water. A defect of a spermatic vein, coupled with a Valsalva maneuver; resulting in a sudden increase in venous pressure, may lead to a localized venous rupture.[3]

Another possible mechanism of injury by sudden lifting could be a result of cremasteric fibers attached to the external surface of the spermatic fascia. This could pull suddenly in consonance with the internal oblique muscle and a tear of the attached loop of fibers might occur with resultant bleeding and hematoma formation.[4]

Lerman noted that most cases of this entity occur in the young adult, with sudden onset of symptoms, after a physically stressful act, with physical examination revealing a tender mass.[3] Our case was consistent with all of the above.

Contrary to the above, Rolnick in 1965 described a case in a sixteen year old, which presented as a painful swelling in the right scrotum, above the testicle, of two weeks' duration. An orchiectomy was performed for a preoperative diagnosis of spermatic cord tumor and an organized hematoma was found.[1] Helmling in 1967, described a case of a 62-year-old, with painless swelling for two months' duration in his right groin. At exploration a spermatic cord hematoma in association with a right indirect inguinal hernia and hydrocele was found.[2] Excluding these two cases, all the presentations and histories were consistent with Lerman's description and our case presentation.

With regard to surgical management, en bloc resection of this lesion is indicated. Ligation of the internal spermatic vein can be done with minimal problem, because of the dual venous system, which will preserve testicular and epididymal function.[7]

Therefore, it seems reasonable that this clinical entity: "Spontaneous Idiopathic Spermatic Cord Hematoma," be a part of the differential diagnosis in a young male, having

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MICHAEL S. GILLIGAN, M.D., 4th year Surgical Resident; SUBHASH O. SHAH, M.D., F.A.C.S., Assistant Attending, General Surgery; both of the Department of Surgery, Bridgeport Hospital, Bridgeport, CT.

sudden onset of pain, with a resulting tender mass, after a physically stressful act. Surgical exploration is warranted and an en bloc resection can be performed without harm to the scrotal contents.

Summary

A case report and review of the literature of Spontaneous Idiopathic Spermatic Cord Hematoma is presented. This clinical entity should be suspected in a young adult having a sudden history of groin pain, with a resultant mass, after a physically stressful act. Surgical management should consist of groin exploration with en bloc resection of the hematoma.

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Fresh-Frozen Plasma

Indications and Risks

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The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office of Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

Fresh-frozen plasma (FFP) is defined as the fluid portion of 1 unit of human blood that has been centrifuged, separated, and frozen solid at −18°C (or colder) within six hours of collection. Other single-donor plasma units, either frozen or liquid, may be substituted for FFP. Indications for these products are interchangeable with those for FFP except for coagulation factor V deficiency. For that reason, the term *FFP* in this statement otherwise applies to all single-donor plasma units. The use of plasma and its products has evolved over a period of four decades. The use of FFP has increased tenfold within the past ten years and reached almost 2 million units annually. This trend may be attributable to multiple factors, possibly including decreased availability of whole blood due to widespread acceptance of the concept of component therapy. Fresh-frozen plasma contains the labile as well as the stable components of the coagulation, fibrinolytic, and complement systems; the proteins that maintain oncotic pressure and modulate immunity; and other proteins that have diverse activities. In addition, fats, carbohydrates, and minerals are present in concentrations similar to those in the circulation. Although well-defined indications exist for the use of FFP in single or multiple coagulation deficiencies, indications for many of its other uses may be empiric.

In an effort to resolve some of the questions surrounding the steadily increasing use of FFP, the National Heart, Lung, and Blood Institute, the Center for Drugs and Biologics of the Food and Drug Administration, and the Office of Medical Applications of Research convened a Consensus Development Conference on FFP Sept. 24 to 26, 1984. After 1½ days of presentations by experts int he field, a consensus panel drawn from the medical professions, blood banking organizations, and the general public considered the evidence and agreed on answers to the following key questions:

1. What are the currently recommended clinical indications for FFP?
2. What are the risks of FFP?
3. What alternative therapies exist?
4. What is the current scientific knowledge regarding the effectiveness of FFP?
5. What directions for future research are indicated?

Panel's Conclusions

The administration of FFP has increased dramatically in recent years despite the paucity of definitive indications for its use. This increase has occurred in the presence of mounting evidence of its potential risks, which include viral hepatitis and possibly acquired immunodeficiency syndrome. Many patients who receive FFP can be managed more effectively and safely with alternative modalities. Appropriate use of FFP must be justified on clinical grounds until better evidence is available. Research to develop safer FFP and alternative therapies is encouraged.

There is no justification for the use of FFP as a volume expander or as a nutritional source. Safer alternative therapies exist.

Fresh-frozen plasma is indicated for some documented coagulation protein deficiencies as well as for selected pa-

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, MD.

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tients who require massive transfusions. It is indicated for patients with multiple coagulation defects as in liver disease, in conjunction with therapeutic plasma exhange for thrombotic thrombocytopenic purpura, for infants with protein-losing enteropathy, and for selected patients with other immunodeficiencies. Its use in most other cases should be discouraged.

Innovative educations efforts are needed to encourage appropriate use.

1. What Are the Currently Recommended Clinical Indications for FFP?

Few specific indications for the use of FFP exist. These indications generally are limited to the treatment of deficiencies of coagulation proteins for which specific factor concentrates are unavailable or undesirable. In addition, circumstances exist in which FFP has been employed and is believed to be of therapeutic value, but data supporting its efficacy are limited or unavailable (eg, multiple coagulation protein deficiencies in the uncontrollably bleeding patient). Because such patients are often critically ill and satisfactory alternative therapy may not be at hand, FFP may be appropriate.

Indications for the use of FFP include the following:

Replacement of Isolated Factor Deficiencies

Fresh-frozen plasma is efficacious for treatment of deficiencies of factors II, V, VII, IX, X, and XI when specific component therapy is neither available nor appropriate. Requirements for FFP vary with the specific factor being replaced. For example, hemostatic levels of factor IX in a patient with severe deficiency are difficult to achieve with FFP alone, whereas patients with severe factor X deficiency require factor levels of about 10% to achieve hemostasis and are easily treated with FFP.

Reversal of Warfarin Effect

Patients who have been given the anticoagulant warfarin sodium are deficient in the fuctional vitamin K-dependent coagulation factors II, VII, IX, and X, as well as proteins C and S. These functional deficiencies can be reversed by the administration of vitamin K. However, when such patients are actively bleeding or require emergency surgery, FFP (or single-donor plasma) can be used to achieve immediate hemostasis.

Massive Blood Transfusion *(>1 Blood Volume Within Several Hours)*

Use of FFP in massive blood transfusion, for which there is less credible evidence of efficacy, appears to have increased in frequency in the past decade, possibly due in part to the relative unavailability of whole blood. Pathological hemorrhage in the patient receiving massive transfusions is caused more frequently by thrombocytopenia than by depletion of coagulation factors. The empiric use of FFP to reverse hemostatic disorders should be confined to those patients in whom factor deficiencies are presumed to be the sole or principal derangement. There is no evidence that the *prophylactic* administration of FFP decreases transfusion requirements in patients receiving multiple transfusions who do not have documented coagulation defects.

Use in Antithrombin III Deficiency

Fresh-frozen plasma can be used as a source of antithrombin III in patients who are deficient in this inhibitor and are undergoing surgery or who require heparin for treatment of thrombosis.

Treatment of Immunodeficiencies

Fresh-frozen plasma is useful in infants with secondary immunodeficiency associated with severe protein-losing enteropathy and in whom total parenteral nutrition is ineffectual. It also can be used as a source of immunoglobulin for children and adults with humoral immunodeficiency. However, the development of a purified immune globulin for intravenous use largely has replaced FFP.

Treatment of Thrombotic Thrombocytopenic Purpura

Fresh-frozen plasma may be beneficial for the treatment of thrombotic thrombocytopenic purpura.

2. What Are the Risks of FFP?

The risks of FFP include disease transmission, anaphylactoid reactions, alloimmunization, and excessive intravascular volume. The potential viral infectivity of FFP probably is similar to that of whole blood and RBCs. The rate of posttransfusion hepatitis—predominantly non-A, non-B—depends on many factors, including donor selection. The incidence of nonicteric and icteric hepatitis following multiple transfusions probably ranges between 3% and 10%. In rare instances, acquired immunodeficiency syndrome is transmitted by blood transfusions and possibly by FFP. Alergic or anaphylactoid reactions can occur in response to FFP administration and may vary from hives to fatal noncardiac pulmonary edema. The potential for alloimmunization is present, as demonstrated by the infrequent formation of Rh antibodies. As with any intravenously administered fluid, excessive amounts of FFP may result in hypervolemia and cardiac failure.

3. What Alternative Therapies Exist?

Evidence indicates that other plasma components (eg, single-donor plasma) that do not meet the criteria of FFP may have adequate levels of coagulation factors and are suitable for patients in whom FFP is indicated. Single-donor plasma is efficacious in the treatment of mild deficiencies of stable clotting factors. It also is of value in treatment of multiple deficiencies as in reversal of warfarin effects or in liver disease.

Safe and effective alternative treatment often exists, so that FFP is no longer the therapy of choice in many conditions. Cryoprecipitate should be used when fibrinogen or von Willebrand factor is needed. For treatment of hemophilia A, cryoprecipitate or factor VII concentrates, heated or unheated, are available. For treatment of severe hemophilia B, factor IX complex is preferable. Both of these concentrates are prepared from pooled plasma, and the risk of virus transmission is high. The factor IX concentrate carries the additional hazard of thrombogenicity.

Crystalloid, colloid solutions containing albumin or plasma protein fraction, hydroxyethyl starch, and dextran are preferable to FFP for volume replacement. The practice of administering both packed red cells and FFP to the same patient should be discouraged, as this adds to the cost and doubles the infection rate. When conditions are appropriate, whole blood should be given.

For nutritional support, amino acid solutions and dextrose are available.

The most important alternative to the use of FFP is a comprehensive program of blood conservation. This includes measures such as autologous donation before elective surgery, the infusion of shed blood, and the realization that in many patients normovolemic anemia is not an indication or transfusion.

Because of the special nature of neonatal requirements for blood and blood products, these issues were not addressed specifically in this report. Nonetheless, efforts should be exerted to continue to avoid undue exposure to multiple donor sources.

4. What Is the Current Scientific Knowledge Regarding the Effectiveness of FFP?

There is little scientific evidence to support the increasing use of FFP in clinical medicine. While FFP is a reliable solution for intravascular volume replacement in acute blood loss, alternative therapies are equally satisfactory and considerably safer. There is no documentation that FFP has a beneficial effect when used as part of the transfusion management of patients with massive hemorrhage. It contains the major plasma proteins, including the labile coagulation factors (V and VIII), but in clinical practice other blood components or derivatives usually provide greater efficacy.

5. What Directions for Future Research Are Indicated?

Research aims should be directed toward the following (no priorities are implied in this sequence):

- A national prospective study to identify the current patterns of use of FFP and related products.
- Better understanding of the balance between coagulation and fibrinolytic systems, their activators and inhibitors, and their roles in the coagulopathies associated with liver disease and massive transfusion.
- Definition of the etiology of uncontrollable hemorrhage in the patient receiving massive transfusions.
- Clinical investigations to identify the factor(s) in FFP that appears to cause beneficial effects in patients who are undergoing apheresis for treatment of syndromes such as thrombotic thrombocytopenic purpura.
- Blood and plasma salvage during operative procedures.
- Production of the safest possible specific plasma constituents and substitutes.
- Processes or methods to eliminate or inactivate viral and bacterial contaminants.
- Technology involving membrane-separation techniques to separate cellular products more effectively.
- Development of an efficient system by which a larger volume of FFP can be collected from a single donation, thus lessening the number of donor exposures in single recipients.

The use of FFP is controlled locally and determined largely by existing practice. Attempts to alter FFP use frequently have been ineffective. The most successful attempts can be attributed to a strong local proponent of modern transfusion practices. Ongoing collaborative efforts, including component therapy workshops involving clinicians and blood banks directors, can do much to alter existing practices. Increased attention to the risks and benefit of component therapy in the medical schools and teaching hospitals also may change the use of FFP. When appropriate, information regarding potential risks and benefits of FFP and other blood products should be made available to patients who receive those products.

Members of the Consensus Development Panel were James L. Tullis, M.D. (chairman), Boston; Barbara Alving, M.D., Washington, DC; Joseph R. Bove, M.D., New Haven, CT; Charles J. Carman, Stow, OH; Ralph B. D'Agostino, Ph.D., Boston; Jessica H. Lewis, M.D., Pittsburgh; Ronald D. Miller, M.D., San Francisco; William W. Monafo, Jr., M.D., St. Louis; Bruce A. Reitz, M.D., Baltimore; J. Gordon Scannell, M.D., Boston; Rev. Sydney Wilde-Nugent, M.T.(ASCP)S.B.B., MDiv., Bethesda, MD.

Members of the Planning Committee were Dennis M. Donohue, M.D. (cochairman), Bethesda, MD; George Nemo, Ph.D. (cochairman), Bethesda, MD; Susan Clark, Bethesda, MD; Richard B. Counts, M.D., Seattle; Edward Lowenstein, M.D., Boston; Charles E. Lucas, M.D., Detroit; Gerald S. Moss, M.D., Chicago; Ernest R. Simon, M.D., Scottsdale, AZ; James L. Tullis, M.D., Boston.

The conference was sponsored by the National Heart, Lung, and Blood Institute, Claude Lenfant, M.D., director; the Office of Medical Application of Research, National Institutes of Health, Itzhak Jacoby, Ph.D., acting director; and the Center for Drugs and Biologics, Food and Drug Administration, Harry M. Meyer, M.D., director.

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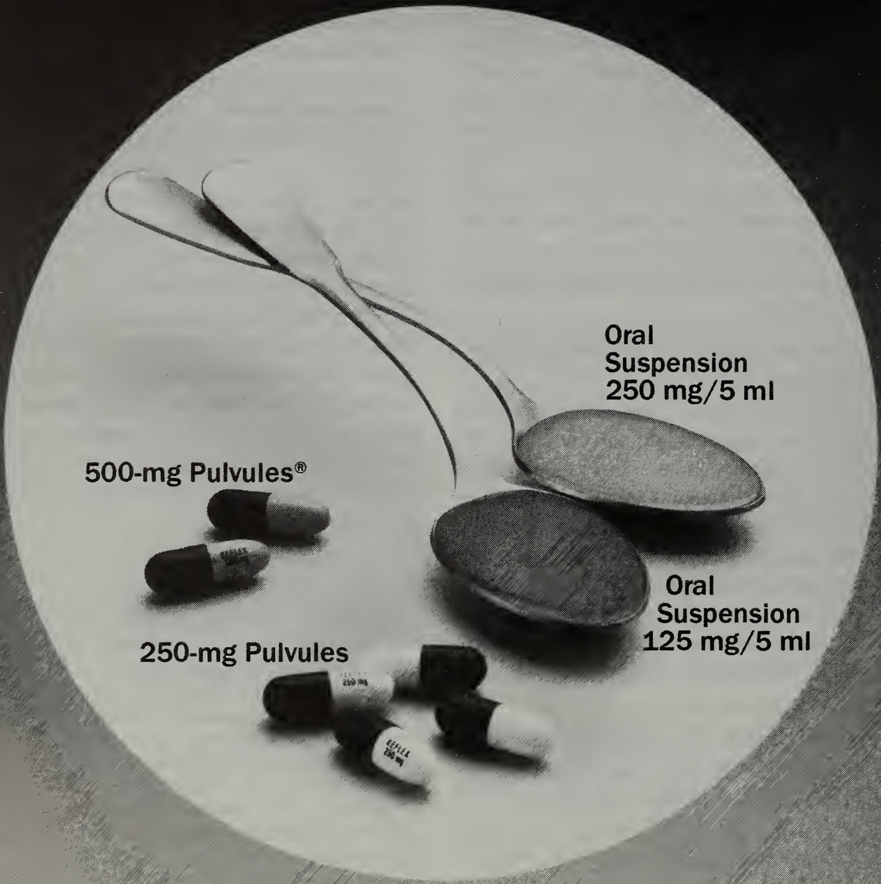

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The Origins of Anesthesia

Part IV

SHERWIN B. NULAND, M.D.

NITROUS OXIDE: A DISCOVERY IN VAIN

Laughing gas had proven not only to be a great source of amusement at private gatherings, but, in the hands of a few show-business-minded entrepreneurs, was a source of income as well. One such enterprising pitchman was Gardner Quincy Colton, an itinerant lecturer who had some medical training and was now traveling about, giving demonstrations of the wonders of electricity and the effects of nitrous oxide gas. The *Hartford Courant* of December 10, 1844, carried his advertisement.

That same evening, a successful young dentist of the town, Horace Wells, brought his wife, Elizabeth, to the laughing gas show. Colton later described these events:

> *One of the young men who volunteered to try the gas was a Samuel A. Cooley, a drug clerk. He came under the influence of the gas and while jumping about, struck his leg on a wooden settee. He bruised it badly. After taking his seat he was astonished to find his leg bloody. He felt no pain until the effects of the gas had worn off. Dr. Horace Wells, one of the town's leading dentists, who had sat next to Cooley . . . noticed this circumstance.*

This account differs slightly from Cooley's own sworn statement, which was published in 1853 in the Walker Report of a Congressional Committee investigating what had by then become the disputed claims over priority in the discovery of anesthesia. However, the basic facts are the same:

> *I, Samuel A. Cooley, a citizen of Hartford . . . Connecticut, depose and say, that on the evening of the 10th day of December, in the year 1844, that one G.Q. Colton gave a public exhibition in the Union Hall, in the said city of Hartford, to show the effect produced upon the human system by the inhaling of nitrous oxide, or laughing gas; and in accordance with the request of several gentlemen, the said Colton gave a private exhibition on the morning of December 11th, 1844, at the said hall; and that the deponent then inhaled a portion of said nitrous oxide gas, to ascertain its peculiar effect upon his system; and that there were present at that time, the said Colton, Horace Wells, C.F. Colton, Benjamin Moulton, and several other gentlemen; . . . and that the said deponent, while under the influence of the gas did run against and throw down several of the settees in the said hall and thereby throwing himself down, and causing several severe bruises upon his knees and other parts of his person; and that after the peculiar influence of said gas had subsided, his friends then present asked if he had not injured himself, and then directed his attention to the acts which he had committed unconsciously while under the operation of said gas. He then found by examination that his knees were severely injured, and he then exposed his knees to those present, and found that the skin was severely abraised and broken; and that the deponent then remarked, "that he believed that a person might get into a fight with several persons and not know when he was hurt, so unconscious was a person of pain while under the influence of the said gas" and the said deponent further remarked, "that he believed that if a person could be restrained, that he could undergo a severe surgical operation without feeling any pain at the time." Dr. Wells then remarked, "that he believed that a person could have a tooth extracted while under its influence and not feel any pain"; and the said Wells further remarked, "that he had a wisdom tooth that troubled him exceedingly, and that if the said G.Q. Colton would fill his bag with some of the gas, he would go up to his office and try the experiment," which the said Colton did: and the said Wells, C.F. Colton, and G.Q. Colton, and your deponent, and others . . . proceeded to the office of said Wells; and that said Wells there inhaled the gas and a tooth was extracted by Dr. Riggs, a dentist then present; and that the said Wells, after the effect of the gas had subsided, exclaimed, "A new era in tooth-pulling!"*

Wells learned how to prepare nitrous oxide from Colton, and then he and Riggs began to work with it. Within a month he had successfully extracted teeth 15 times without pain, and felt that he was ready to introduce his method "into the hands of proper persons" who would know how to do appropriate experiments and make the best use of the new discovery.

Wells travelled to Boston, then as now one of the foremost centers of medical thought in America. With the aim of obtaining an introduction to the leading surgeons of that city, he sought the aid of a former student of his,

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SHERWIN B. NULAND, M.D., Associate Clinical Professor of Surgery, Yale University School of Medicine. Dr. Nuland is Literary Editor of *Connecticut Medicine*. This is Chapter VII of Dr. Nuland's book *The Origins of Anesthesia*.

William Thomas Green Morton, with whom he had had a brief period of professional partnership. Morton introduced Wells to Drs. George Hayward and John Collins Warren. What happened as a result of that introduction is best described in a letter written years later and addressed to the Editor of the *Hartford Courant,* December 9, 1846:

> Hartford, December 7, 1846
>
> *Mr. Editor:* You are aware that there has been much said of late respecting a gas, which, when inhaled, so paralizes the system as to render it insensible to pain. The Massachusetts General Hospital have adopted its use, and amputations are now being performed without pain. Since Drs. Charles T. Jackson and W.T.G. Morton, of Boston claim to be the originators of this invaluable discovery, I will give a short history of its first introduction that the public may decide to whom belongs the honor.
>
> While reasoning from analogy, I was led to believe that the inhaling of any exhilarating gas, sufficient to cause a great nervous excitement, would so paralyze the system as to render it insensible to pain, or nearly so; for it is well known, that when an individual is very much excited by passion he scarcely feels the severe wounds which may be at the time inflicted, and the individual who is said to be "dead drunk," may receive severe blows, apparently without the least pain, and when in this state is much more tenacious of life than when in the natural state. I accordingly resolved to try the experiment of inhaling an exhilarating gas myself, for the purpose of having a tooth extracted. I then obtained some nitrous oxide gas, and requested Dr. J.M. Riggs to perform the operation at the moment when I should give the signal, resolving to have the tooth extracted before losing all consciousness. This experiment proved to be perfectly successful—it was attended with no pain whatever. I then performed the same operation on 12 or 15 others with the same results.
>
> I was so much elated with this discovery that I started immediately for Boston, resolving to give it into the hands of proper persons, without expecting to derive any pecuniary benefits therefrom. I called on Drs. Warren and Haywood (sic: the Dr. Haywood referred to in this paper is actually Dr. George Hayward. Wells confuses him with Dr. C.F. Haywood, who was House Surgeon in the Massachusetts General Hospital), and made known to them the result of the experiments I had made. They appeared to be interested in the matter and treated me with much kindness and attention. I was invited by Dr. Warren, to address the Medical Class upon the subject, at the close of his lecture. I accordingly embraced the opportunity, and took occasion to remark that the same result would be produced, let the nervous system be excited sufficiently by any means whatever; that I had made use of nitrous oxide gas or protoxide of nitrogen, as being the most harmless. I was then invited to administer it to one of their patients, who was expecting to have a limb amputated. I remained some two or three days in Boston for this purpose, but the patient decided not to have the operation performed at that time. It was then proposed that I should administer it to an individual for the purpose of extracting a tooth. Accordingly, a large number of students, with several physicians, met to see the operation performed—one of their number to be the patient. Unfortunately for the experiment, the gas bag was by mistake withdrawn much too soon, and he was but partially under its influence when the tooth was extracted. He testified that he experienced some pain, but not as much as usually attends the operation. As there was no other patient present, that the experiment might be repeated, and as several expressed their opinion that it was a humbug affair, which in fact was all the thanks I got for this gratuitous service, and I accordingly left the next morning for home.—While in Boston, I conversed with Drs. Charles T. Jackson and W.T.G. Morton, upon the subject, both of whom admitted it to be entirely new to them. Dr. Jackson expressed much surprise that severe operations could be performed without pain, and these are the individuals who claim to be the inventors. When I commenced giving the gas, I noticed one very remarkable circumstance attending it, which was, that those who sat down resolving to have an operation performed under its influence, had no disposition to exert the muscular system in the least, but would remain quiet as if partially asleep. Whereas, if the same individual were to inhale the gas under any other circumstances, it would seem impossible to restrain them from exertion.
>
> I would here remark, that when I was deciding what exhilarating agent to use for this purpose, it immediately occurred to me that it would be best to use nitrous oxide gas or Sulphuric Ether. I advised with Dr. Marcy, of this city, and by his advice I continued to see the former, as being the least likely to do injury, although it was attended with more trouble in its preparation. If Drs. Jackson and Morton, claim that they used something else, I reply that it is the same in principle if not in name, and they cannot use anything which will produce more satisfactory results, and I made these results known to both of these individuals more than a year since. After making the above statement of facts, I leave it to the public to decide to whom belongs the honor of this discovery.
>
> Yours truly,
> HORACE WELLS, Surgeon Dentist

"Several expressed their opinion that it was a humbug affair" was an incomparable bit of understatement. What had actually happened was that poor Wells retreated from the amphitheater amidst the jeers of the assembled onlookers. Of the epithets that assaulted his ears, "humbug" was among the least indelicate. He left Boston in defeat, in humiliation, and, in his own eyes, in disgrace. This letter was not written by a man with unimpaired psychological faculties. The failure at the Massachusetts General Hospital had a devastating effect upon the spirit of Horace Wells. Immediately upon returning from the Boston fiasco he put this notice in the *Hartford Courant:*

> *Cottage to let—H. Wells, wishing to give up housekeeping, will let his cottage on Lord's Hill at a very low rent, to one who will pay some attention to the shrubbery and trees on the premises. Possession given the first of April.*

On April 7, the following appeared in the *Courant:*

> *Dental Notice—Having relinquished my professional business for the present, in consequence of ill health, I do with pleasure refer those who have confidence in*

> *me, to Dr. J.M. Riggs, whose professional qualifications are not surpassed by any dentist in the country.*

Unable to practice dentistry, Wells turned his nervous energy to several money-making projects, with indifferent success. On October 19, 1846, just after carrying out the successful demonstration with ether in Boston, William Morton wrote the following letter to his former partner, which, while appearing innocent enough, added substance to the fabric of his misery:

> *Friend Wells. Dear Sir, – I write to inform you that I have discovered a preparation by inhaling which a person is thrown into a sound sleep. The time required to produce sleep is only a few moments, and the time in which persons remain asleep can be regulated at pleasure. While in this state, the severest surgical or dental operations may be performed, the patient not experiencing the slightest pain. I have perfected it, and am now about sending out agents to dispose of the right to use it. I will dispose of a right to an individual to use it in his own practice alone, or for a town, county or state. My object in writing to you is to know if you would not like to visit New York and the other cities, and dispose of rights upon shares. I have used the compound in more than a hundred and sixty cases in extracting teeth; and I have been invited to administer to patients in the Massachusetts General Hospital, and have succeeded in every case.*

Morton and John Collins Warren had ushered in the era of surgical anesthesia; Wells, lacerated beyond recovery by his former protégé's success and acclaim, began his raging battle for recognition with that December 9, 1846 letter to the *Courant.*

Shortly after the letter was published, Wells, like Henry Hickman before him, determined to seek an audience in Paris, and traveled there to petition the Académie Royale de Médicine and the Académie des Sciences. It is uncertain how extensively the two Académies investigated his claims at that time, but both societies did publish extracts from his petitioning letter in their proceedings.

Wells had gone to Paris with no definite evidence in the form of testimonials, and at the time he returned to Hartford in March 1847, the outlook for his recognition appeared bleak. Immediately upon his ship arriving in Boston he began assembling sworn statements and within a few days was back in Hartford where he collected more.

On March 30, 1847, only a week after his disembarkation, he published his only separate publication on anesthesia, entitled *History of the Discovery of the Application of Nitrous Oxide Gas, Ether and other Vapors,* containing the testimonials he had gathered. The originals of the supporting letters were sent to Paris to be reviewed by the Académies.

Neither the letter, nor the trip to Paris, nor the *History* seemed to do much to reverse the tide that favored Morton's priority. Leaving his wife and child behind in Hartford without funds for their support, Wells, by now crazed with the injustice of his fate, moved to New York, determined to continue his experiments with nitrous oxide, with ether, and with chloroform, which latter gas had been introduced as an anesthetic by James Young Simpson in November, 1847. In the January 17, 1848 issue of the *New York Evening Post,* the following advertisement appeared:

> *H. Wells, surgeon dentist, the discoverer of "Letheon," having removed to New York, will give gratuitous advice respecting the use of chloroform, nitrous oxide gas, and "Letheon," as applied to the extraction of teeth from 10 o'clock A.M. until 3 o'clock P.M. Residence 120 Chambers Street, West of Broadway.*

It was only four days later, ironically on his 33rd birthday, that Horace Wells was thrown into the Tombs prison, the charge against him that the inventor of nitrous oxide anesthesia had hurled sulfuric acid at some streetwalkers on Broadway. His degradation seemed to be complete.

But there was one final act in the drama, of a nature so tragic in its dimensions that the irony of its epilogue not only does not diminish its ghastliness, but outlines it and magnifies it: on January 22, 1848, Horace Wells, whose experiments had made him a chloroform addict, inhaled just enough of a smuggled bottle of that compound to make himself partly insensible, and then ended his life by drawing a razor across his left femoral artery. This letter was found in his cell:

> *Sunday, evening, 7 o'clock*
>
> *I again take up pen to finish what I have to say. Great God! Has it come to this? Is it not all a dream? Before 12 o'clock tonight I am to pay the debt of nature. Yes, even if I was to go free tomorrow, I could not live and be called a villain. God knows I am not one . . . Oh! my dear wife and child, whom I leave destitute of the means of support – I would still live and work for you, but I cannot – for if I were to live on, I should become a maniac. I feel that I am little better than one already . . . .*

And now the epilogue. When Wells went to Paris, he had been befriended there by an American dentist, C. Starr Brewster, who helped him to present his case to the two Académies and to the Paris Medical Society. Twelve days after the suicide of Wells, the following letter arrived for him from Brewster:

> *My Dear Wells:*
>
> *I have just returned from a meeting of the Paris Medical Society where they voted that to Horace Wells of Hartford, Connecticut, United States of America is due the honor of having successfully discovered and successfully applied the first use of vapors or gases whereby surgical operations could be performed without pain . . . .*

Thus, surgical anesthesia's second martyr, like his predecessor Henry Hickman, received a recognition that came too late to save his life or to give balm to his troubled mind.

Demographic Analysis: A Marketing Must

SCOTT H. SHARE, M.B.A., LEIF C. BECK, LL.B., CPBC,
GEOFFREY T. ANDERS, J.D., C.P.A., AND PATRICIA DARCY ALEXANDER

There are numerous reasons why physicians seek help through marketing. While doctors who actually suffer a declining or stagnant patient base are obvious candidates, many successful physicians and group practices are also becoming concerned over such potential problems. There is good reason for concern. A recent study revealed that office-based M.D.'s experienced, on average, a 20% decline in patient visits between 1974 and 1982.[1]

Unemployment and the souring economy have in some cases forced people to forego physician visits purely for economic reasons. But even the typical medically aware patient now finds vastly more doctors and alternative health care providers available and competing for those visits.

Physicians and groups who wish to become successful and/or to maintain their success levels for many years hence can no longer ignore the consequences of these developments-they should realize that effective business concepts can arrest or prevent patient erosion and strengthen their practices.

Others have turned to commercial thought for different reasons. Healthy practices often view marketing as a way to stay ahead of the competition. Physicians just completing their residencies may utilize marketing and market research techniques to help select future practice locations.

Established physicians who wish to either relocate their practices or establish satellite offices also use these techniques to help make practice location decisions. Still others turn to marketing to better position their practices,[2] introduce new or refined treatment/diagnosis procedures, increase consumer awareness about health care.

How Demographics Can Help You

For whatever reason marketing is undertaken, it is important that an often ignored component-*demographic analysis*—be incorporated into a physician's marketing plan. In our experience, many physicians balk at or simply refuse to engage in analysis of area demographics. Some claim they already know what is going on in their service areas; others question the importance or usefulness of demographic data.

Still other doctors simply insist on making major changes in their practices regardless of what demographic analysis may or may not tell them. This could be foolish and costly since a mistaken decision can be disastrous either in poorly spent dollars or in lost opportunities. Those who ignore or reject the importance of demographic analysis would do well to review the historical significance of demography.

Virtually all businesses and industries have used demographic information as a means of identifying target markets for their products and services.[3] The health care industry is no exception; most hospital planning departments, for example, make major efforts to maintain and analyze demographic statistics in order to target program and service innovations to the needs of the community.

A medical practice, whether you like to admit it or not, is a business. Physicians can save time, money, energy and potential heartache by first investigating and analyzing the demographic and socioeconomic characteristics of the area(s) they are currently serving and/or wish to serve. In addition, private practitioners can greatly benefit from demographic studies in order to best compete against their growing competition—including hospitals, HMO's, clinics, and other practices.

Anyone planning to devise a comprehensive marketing "game plan" must first examine the demographic data, which include the following criteria.

- Total population or current and/or intended service area(s)
- Rate of change of population
- Age distribution

The authors are the principal consultants of Health Care Marketing Associates, Ltd., Bala Cynwyd, PA. An affiliate of The Health Care Group, deals exclusively with problems confronting medical practices.

- Racial/ethnic composition
- Employment status/income levels
- Housing information
- Fertility ratios

Let us consider each of these factors in a demographic analysis.

Population

Because a marketing plan will in some way involve reaching out to area residents, the physician must know the size of his or her audience. Determining an area's population requires accurate, up-to-date information since approximately 20% of the American population moves in any given year.[4] For this reason, it is important that the physician rely upon facts, not impressions, when assessing an area's population.

The overall size of an area's population will help determine certain components of the marketing plan, including its scope and comprehensiveness. It will also help identify acceptable expenditure levels for carrying out the plan. In common parlance, you should be critical of how much "bang" you will get from your "buck."

Population Changes

The mobility of U.S. citizens leads to continuing fluctuations in population levels of communities and towns throughout the country. Often these changes are slow and gradual, almost imperceptible to the casual observer. However, the physician or group which keeps abreast of demographic data can spot changes before other area practitioners and thus gain an important competitive edge from the observations.

For example, suppose a successful internist is interested in helping his practice grow by opening a second office. Rather than competing head-to-head in a well-populated but physician-saturated location, the internist considers outlying, less populated suburban or rural areas where competition is not as great a factor. He could then obtain current and historic population statistics on several potential areas as well as population projections if available; these data would reveal not only each area's current population but also the rates of population change over time.

Using this information, the internist might decide to open a second office in a town of 5,000 rather than a town of 10,000 if the smaller town has a 50% annual growth rate as opposed to only a 5% annual growth rate for the larger town. The smaller town might very well overtake the larger town in terms of total population within three years, thus possibly being the doctor's better choice.

Because office location decisions and other planning/marketing strategies require large time and money investments, population changes should be investigated *before* any further commitments are made—before a mistaken step might be taken.

Age Distribution

The age distribution of an area's population is terribly important to a practicing physician, particularly the specialist. Many specialties, by design, cater to particular age groups.

Pediatricians and child psychiatrists will obviously favor locations with high percentages of people under the age of eighteen, while urologists, ophthalmologists and geriatric specialists would be interested in areas with high concentrations of elderly citizens. Obstetricians would look favorably upon areas with high percentages of women of child-bearing age. Family and general practitioners lately seem to be targeting their services more and more to younger people. Consequently, almost any specialist should examine an area's age distribution to see if it is satisfactory or desirable for his particular practice.

Changes in age distribution over time should also be noted in locations of interest. Areas with age groups that have grown in proportion to other age groups should be noted. This information offers the physician foresight into what an area's age distribution will be in the future, so he can plan and market his services accordingly.

Racial/Ethnic Composition

In most instances, the general race and ethnic composition of a community may be common knowledge and would not require much in the way of demographic analysis.

A general awareness of the races and ethnic groups in your general practice area is important in order for the physician to best serve current and potential patients, as well as to optimally plan for and maintain practice resources.

Employment Status/Income Levels

Knowledge of employment characteristics in a particular area is helpful for a number of reasons. An wareness of the major employers of an area can give the physician good indications of what type of health problems might be prevalent in the community.

For example, if manufacturing concerns dominate the employment environment, there might be higher rates of industrial accidents such as fractures; orthopedic specialists would take note of this.

If a significant number of area residents are employed by industries involved with the handling, processing, or disposal of hazardous wastes, the incidence of chemical burns, radioactive poisoning and/or certain types of cancer might be higher than in the general population. Physicians who note the presence of these potential health hazards might promote community education (e.g. seminars) and preventive measures (e.g. cancer screenings) as part of their marketing strategy.

If demographic research reveals that white collar workers dominate the community, the physician might look into the possibility of offering such services as

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Income level figures can often be reliable indicators of the market for medical services in a particular community. Areas with relatively high family income levels might be good places to promote the services of a plastic surgeon, or of weight loss and stop-smoking programs. On the other hand, communities with relatively lower average family incomes, often indicative of less educated populations, could have a greater need for education and preventive medical services. In either case, the physician could benefit from this knowledge because it can help determine the mix of programs and services that he/she should make available.

Housing Information

Knowledge of the number and rates of or change of households and housing starts can be beneficial to the marketing medical practitioner for several reasons. In addition to a growth in population, an increase in the number of households and housing starts is an indication of a healthy, growing community. A stagnation or decrease in either category could indicate the beginning (or acceleration) of a community's decay.

The type of housing in a community is also of interest. A surge in apartment construction, for example, could mean an influx of young singles or married couples; many of these people will have no knowledge of or ties to the medical community. The marketing physician should view these people as a prime source of new patients and structure his marketing strategy accordingly. The existence of a retirement community near a physician's office, as another example, could introduce several new program and service opportunities.

Fertility Ratios

The fertility ratio can be particularly important to primary care physicians. Calculated and made available by the U.S. Census Bureau, the fertility ratio represents the number of children ages 0–5 per one thousand women ages 15–49. For example, a fertility ratio of 300 would mean that, in that particular community, there are 300 children between the ages of zero and five for every one thousand women of child-bearing age.

This statistic can be extremely useful to pediatricians, obstetricians and other primary care physicians in that it allows, at a glance, the evaluation and comparison of communities in terms of their recent, current and future "youth" population.

Where To Obtain Information

The U.S. Bureau of the Census is a prime source for most of the demographic characteristics of interest. This organization, which is part of the U.S. Department of Commerce, collects, tabulates and publishes data on population size, age distribution, employment status, median income, racial/ethnic composition, fertility ratios and housing information. The statistics are abstracted from census information every ten years and are accessible at most local libraries, city halls or chambers of commerce.

Demographic information made available by the Census Bureau is broken down by state, county and township designations. Township and borough statistics are almost always the most useful for marketing analysis since they allow physicians to more accurately, efficiently, and effectively target their respective markets.

A physician seeking to augment available census information, he/she might develop a questionnaire for current and/or prospective patients. Such a questionnaire, accompanied by an explanatory letter, could be distributed to all current patients and new residents of the community. It could ask respondents to reply to basic demographic inquiries (age, sex, residence, income, employment, dependents, etc.) and thus allow the physician to develop his/her own profile of current/prospective patients. The profile would in turn help a doctor to effectively develop and target new programs and services to the community.

Profiles of industry and employment by geographic area are readily available from a number of sources, including local, county or regional development or planning commissions (including so-called "IDC's"—industrial development commissions) as well as national publications such as Dun and Bradstreet's *Million Dollar Directory*. Available data usually includes type of industry, location, number of employees and annual sales volume. These data could well influence decisions that the marketing physician makes concerning his or her practice's direction.

Updating Your Demographic Information

Physicians must update their demographic profiles on a regular basis. While census data are essential and reliable, most of the information is collected only at ten-year intervals and made public only after many months of tabulation and analysis; thus, it does not represent actual present-day statistics. Thus while census information is essential to demographic analysis, it must be conscientiously complemented with additional information sources.

Local concerns such as large industries, hospitals and city governments often undertake demographic studies for their own information; many are willing to share this information upon request. Hospitals, in particular, are often pleased to share information with their medical staff members or even to undertake some original research at their physicians' request. Hospitals themselves are often fiercely competitive for admitting physicians and may look upon such requests as opportunities to help physicians increase admissions.

The Federal Government also periodically makes available census updates, which are available upon request. In addition, the Census Bureau prepares occasional population projections based on previous census information; these forecasts are fairly reliable and often offer the best available glimpse of what the future holds for particular demographic characteristics. Local planning agencies also tend to devise their own population projections for nearly areas; these can also be used if desired.

Physicians should also advise their staffs, families and friends to keep them apprised of new developments in the community, such as new housing starts, school openings or closings, new or expanding industry and the like. And the doctors obviously should stay alert to new developments themselves—smart marketing decisions often flow from personal attentiveness to one's environment.

Who Should Do Your Study

If so inclined, a physician could personally undertake a demographic analysis himself. The study is, however, time-consuming enough that devoting a doctor's time away from revenue-generating hours may be uneconomic. Hence it is often better for others to accomplish the task. Sometimes the physician's spouse, office manager or high school/college aged offspring can undertake much of the initial collection and tabulation that is necessary for a demographic study, for there is much pure errand-running to track down the information items.

Another possibility is to hire an outsider to accomplish the demographic analysis. A professional should be able to provide a more timely, complete and thorough analysis because he or she has done it before; secrets of the trade such as shortcuts to take, pitfalls to avoid, data that is important and that which can be ignored come with experience. In the long run, it may actually be cheaper to obtain a professional's undertaking since it minimizes the physician's time in the process.

Conclusion

Regardless of who undertakes or oversees such a project, demographic analysis is an integral part of a physician's or medical group's overall marketing strategy. Such analysis can yield valuable information about your current and prospective service areas in a time- and cost-effective manner. In today's competitive health care environment, that type of information can help you decide exactly how to "target" your own medical practice efforts for most satisfying results.

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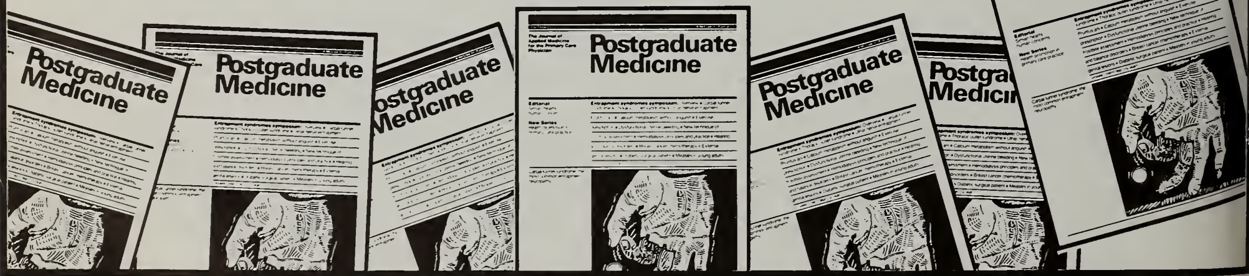

Medicare Assignment: Recent Trends and Participation Rates

AMA CENTER FOR HEALTH POLICY RESEARCH

Medicare, the nation's health program for the elderly and disabled, is now one of the fastest growing portions of the federal budget. Within Medicare, expenditures on physicians' services are growing faster than Medicare expenditures overall. Thus, recent national budgetary pressures have focused the attention of federal legislators and policy makers on Medicare and, in particular, payments to physicians.

Specifically, physicians' Medicare reimbursements have been frozen and a hospital admission review program has been instituted, which is expected to switch some minor surgery from the hospital to a variety of outpatient settings. The federal government has enacted several measures to increase the Medicare assignment rate. In order to accomplish this, the federal government initiated the participating physician program as part of the Deficit Reduction Act. This act establishes a special category of physicians, "participating physicians," who agree to accept all their Medicare patients on an assigned basis. With these new policies, the government wishes to accomplish the goal of cost containment, while preserving access to quality medical care for all beneficiaries.

Changes in the Medicare program may have an impact on physicians' involvement in Medicare and patients' access to care. This report, which is part of a series of reports on the Medicare program, examines:

- recent trends in physician assignment rates; and
- the percentage of physicians who chose to become "participating physicians," by specialty and previous assignment history.

The data are drawn from AMA's second quarter 1982 and 1984 annual core surveys and fourth quarter 1984 SMS survey.

Assignment Patterns of Physicians—Recent Trends

When a physician accepts a Medicare patient on assignment, he or she accepts the "allowable" charge set by Medicare as full payment. This charge is computed by a complex formula which includes geographical averages, the physician's customary fee and other factors. Medicare pays 80 percent of the allowed charge, while the patient pays 20 percent. If the patient is not accepted on assignment, he or she has to pay the 20 percent, plus any amount that the physician charges over the Medicare allowable charge.

Table 1 presents information on the percentage of physicians that accept some patients on assignment and the average percentage of Medicare patients accepted on an assigned basis for the years 1982 and 1984. For the all physicians category more physicians accepted assignment in 1984 than in 1982—83.9 percent compared to 75.6 percent. Furthermore, the average percentage of patients assigned rose from 39.9 percent in 1982 to 51.3 percent in 1984.

For 1984, physician assignment behavior shows considerable regional as well as specialty variation. The percentage of physicians that assign any Medicare patients varied from 78.2 percent in the North Central region to 89.0 percent in the Northeast. Likewise, physicians in internal medicine had the highest percentage of physicians that assigned any patients, 91 percent. General/family practitioners assign fewer patients, 43 percent on average, than either of the other three specialty groups. On a regional basis, the average percentage of patients assigned ranges from a low of 43 percent in the North Central region to a high of almost 65 percent in the Northeast.

An alternate way to examine the assignment issue is to look at the distribution of assignment rates over time. Table 2 contains information on the assignment rate distribution for 1982 and 1984. The percentage of non-federal patient care physicians that did not accept assignment for any patients declined from 24.4 percent in 1982 to 16.1 percent in 1984. Moreover, the percentage of physicians that assign all of their Medicare patients rose from 20.5 to 32.1 percent over this period.

Medicare Participation Rates

In an attempt to increase the number of Medicare claims that are assigned, the federal government has enacted the participating physician program as part of the Deficit Reduction Act of 1984. Simply, physicians have the option of assigning on a case-by-case basis as was done in the past, or they may elect to participate, i.e., sign an agreement to accept *all* Medicare patients on assignment.

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

Table 1

PHYSICIAN'S ASSIGNMENT PATTERNS BY SPECIALTY AND REGION, 1982 AND 1984

	Of Physicians Who Treat Some Medicare Patients			
	Percent of Physicians Who Accept Assignment for any Patients		*Average Percent of Patients Assigned*	
	1982	*1984*	*1982*	*1984*
ALL PHYSICIANS	75.6%	83.9%	39.9%	51.3%
Region				
Northeast	78.4	89.0	49.2	64.8
North Central	71.9	78.2	38.4	43.2
South	76.7	83.5	39.7	50.5
West	74.9	85.3	32.2	47.9
*Specialty**				
GP/FP	63.9	79.5	32.2	43.0
Internal Medicine	80.1	91.0	39.9	51.0
Surgical	80.1	85.0	39.9	51.3
Other**	74.3	81.5	46.6	56.8

*Pediatricians excluded due to their limited contact with Medicare patients. **Includes psychiatrists, radiologists, anesthesiologists, and pathologists

Source: Socioeconomic Monitoring System, Second Quarter 1982 and Second Quarter 1984 data, AMA.

Incentives to participate include being the first to receive fee increases, benefits from federal publicity efforts, and a federal hotline that refers recipients to participating physicians.

Table 2

DISTRIBUTION OF ASSIGNMENT RATES FOR PHYSICIANS WHO TREAT SOME MEDICARE PATIENTS

Percent of Patients Accepted on Assignment	*1982*	*1984*
Zero	24.4	16.1
1-50	41.0	37.7
51-99	14.1	14.0
100	20.5	32.1

Source: Socioeconomic Monitoring System, Second Quarter 1982 and Second Quarter 1984 data, AMA.

Table 3

PERCENT OF PHYSICIANS WHO DECIDED TO BECOME MEDICARE PARTICIPATING PHYSICIANS

	Percent of Sampled Physicians	*Percent in Each Category Who Elected to Participate*
ALL PHYSICIANS	100%	37.2%
Percent of Medicare patients assigned previously:		
None assigned	15.9	20.1
1-50% assigned	36.9	27.0
51-99% assigned	12.7	48.0
100% assigned	20.4	76.7
*Specialty**		
GP/FP	17.3	33.0
Internal Medicine	15.7	41.2
Surgical	28.4	37.7
Other**	31.9	42.5

*Pediatricians excluded due to their limited contact with Medicare patients. **Includes psychiatrists, radiologists, anesthesiologists and pathologists.

Source: Socioeconomic Monitoring System, Fourth Quarter 1984 Data, AMA.

Overall, data from the fourth quarter 1984 survey indicated that over one-third of all non-federal patient care physicians have become Medicare participating physicians (37.2%). Table 3 shows the percentages of physicians participating, broken down by specialty and previous assignment history. The first column provides each category's percent of the physicians sampled by past assignment history and specialty. The second column is the percent of physicians in the category who decided to participate by October 1, 1984. The physicians' past assignment rate had a clear relationship to whether the physician would participate. As the percentage of Medicare patients previously assigned increases from 0 to 100 percent the probability that a physician signed a participating agreement increases from 20 to 77 percent. Analyzing the participation rate data by specialty reveals that physicians in the "other" specialty category and the internal medicine category have the highest participation rates, 42.5 and 41.2 percent respectively.

To date, it is too early to determine the full impact of the Deficit Reduction Act on physicians and their Medicare patients. SMS data reveal, however, that the assignment rate has increased steadily and that participation rates are strongly correlated with previous assignment history. According to SMS data, the trend indicates that more Medicare patients will be treated on an assigned basis in the future, thereby preserving access to quality care, while holding down out-of-pocket expenditures to the elderly.

Report prepared by Department of Health Systems Analysis. Data prepared and analyzed by Janet Willer, Staff Associate.

Data for the first section of this report is from the 1982 and 1984 Socioeconomic Monitoring System Core Surveys. SMS surveys non-federal patient care physicians. The interviews were with 3817 and 4002 physicians, and the response rates were 60.3% and 61.9% respectively. Data for the second section is from the fourth quarter 1984 survey. 1212 physicians were interviewed; the response rate was 65.1%.

Month in Washington

PROPAC Recommendations

Medicare rates in fiscal 1986 would rise by an estimated 1% to 3% under a formula recommended by a panel Congress set up to advise Medicare officials on future rates and changes in Medicare's prospective pricing system.

The recommendation by the Prospective Payment Assessment Commission (PROPAC) contrasts with a Reagan Administration budget proposal to freeze the 1986 rates for each of the program's 468 diagnosis related groups. Payments to hospitals in fiscal 1986 would be from $320 to $960 million greater under the PROPAC proposal than in the Administration plan.

When Congress created PROPAC in the same law that set up the DRG payments, it said that after 1986, the Secretary of Health and Human Services should consult with PROPAC in the development of new rates. HHS is not required to accept PROPAC's advice, however, and the reaction of Congress and the Reagan Administration to the commission's recommendations suggested 1986 rate increases could serve as a key test of PROPAC's influence and future.

Adopted unanimously by the 15 PROPAC members, the rate update is one of 21 recommendations included in a report that PROPAC presented to Congress April 1. Other recommendations call for improving a wage index that many believe is unfair to rural hospitals; development of special rates for hospitals that treat an especially large percentage of indigent patients; and "recalibration" or revision of the relative weights of the DRGs in 1986.

The commissioners also studied several procedures where the current DRG assignments and weights have been questioned. They concluded that cases in which percutaneous transluminal coronary angioplasty (PTCA) is the principal procedure should be temporarily reassigned from DRG 108 to DRG 112. Study on this issue will continue, however, and the procedure may be reassigned to DRG 125 at some later date.

On the other hand, the PROPAC members recommended, the DRGs involving cardiac pacemaker implants, bone marrow transplantation, and cataract extractions and intraocular lens implants should not be altered until the DRS weights are recalibrated. PROPAC has submitted an additional report on its pacemaker recommendations to Congress and will continue to study all of the above procedures.

* * * *

PROPAC Pacemaker Report

Despite indications that flawed data may have been used to construct Medicare diagnosis related groups (DRGs) affecting cardiac pacemaker implantations, no adjustments in the pacemaker DRGs should be made at the present time, the Prospective Payment Assessment Commission (PROPAC) has told Congress.

In a report released earlier this month, the commission pledged continued watchfulness for possible quality deterioration in pacemaker services in the future. The advisory group also will do further studies to try to determine whether DRG adjustments for wages, location and other factors may lead to unjustified pacemaker payment variations that discriminate against certain types of hospitals.

The report recommended nonetheless that any adjustments in the four pacemaker DRGs (115, 116, 117 and 118) be made only as part of the overall recalibration of the weights used as a measure of the relative resource use of each of the 468 DRGs. Congress has directed that the weights be recalibrated for fiscal 1986 and at least every four years thereafter.

Mandated in the 1984 Deficit Reduction Act, the PROPAC pacemaker report estimated that pacemaker DRG payments cover from 84% to 109% of hospital costs for these services. Since this compared to an average of 90% for DRG payments for all hospital discharges, PROPAC concluded that the current pacemaker payments are "appropriate."

PROPAC did find problems in the 1981 data used to construct the pacemaker DRGs. The report suggested that some of the problems may disappear under the DRG system's incentives for better record-keeping and more efficient care, however. It concluded that a special adjustment was not justified now because the same problems affect all other DRGs as well and because some of the data may have understated DRG costs while other data overstated it, leaving the overall impact on the pacemaker prices unclear.

The report entitled "A Report on the Appropriateness of Medicare Hospital Payments for Pacemaker Implan-

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Prepared by the Washington, D.C.
Office of the American Medical Association

tation" was presented to the House Ways and Means and Senate Finance Committees. It is available by writing to PROPAC at 300 7th Street, SW, Suite #301B, Washington, DC 20024 or by calling 202/453-3986.

* * * *

Florida HMOs

The Reagan Administration proceeded with a new Medicare HMO option even though it was aware of administrative snarls that indicated that "the federal government cannot operate the program in one state let alone the other 49," Rep. Larry Smith (D-FL) has charged.

Smith based his comments on a General Accounting Office study he requested after problems developed in four Medicare demonstration HMOs in south Florida. The study pointed to program administration difficulties at the Florida Blue Cross and Blue Shield Plan and within the Health Care Financing Administration.

HCFA retorted that the problems GAO identified in Florida "do not currently exist" and said it is "unfortunate" that the GAO left the "impression that problems experienced in the demonstration projects have either been ignored nor not corrected, which is not the case."

A Blue Cross and Blue Shield spokesman said the plan had not yet seen the GAO report.

The four Florida HMOs have enrolled about 112,000 Medicare members, or about half of all Medicare enrollees in 26 HMO demonstration plans that served as a pilot for a Medicare prospective payment option. The option, which went into effect February 1, is expected to encourage up 800,000 Medicare beneficiaries to switch to HMOs or similar plans in the next few years and to double the current number of Medicare HMO enrollees. Concerns such as those raised in Florida had prompted Rep. Smith and the American Medical Association to seek delays in the implementation of the option.

Although a later GAO study will look at the quality of care provided in the HMOs, HCFA estimates that about 96% of the complaints about the Florida HMOs have revolved around administrative issues, particularly the enrollment and disenrollment procedures.

The current study found two basic flaws in the Florida demonstration. The first involved an error-ridden process for coordinating Medicare HMO payments with the traditional Medicare program's payment. The second centered on a four to eight week waiting period between the time the beneficiary enrolled in or left the HMO and the date on which his new coverage began.

A central factor in the payment coordination problem, according to GAO was a faulty federal computer system that could not identify whether a Medicare beneficiary was an HMO member until 16 to 37 days after the individual had enrolled in or disenrolled from the HMO.

The federal record of enrollment is important to enforce a provision "locking" beneficiaries in to the services of the HMO and preventing payments for both the HMO coverage and the non-HMO services that would have been provided under the traditional Medicare plan.

In looking at about nineteen months worth of claims for the Florida HMO members, GAO found that of 6,737 Medicare beneficiaries (or 6.4% of the Medicare HMO enrollees) ran up about $2.6 million worth of bills for physician services outside of and unauthorized by the HMO.

About $700,000 of the claims were paid by the Blues plan even though they should have been denied and even though in some cases the HMO had also paid for these services. Another $1.9 million in claims were correctly denied by the Blues, but caused problems for some beneficiaries who faced substantial bills that for 64 patients totalled $5,000 each or more.

In the majority (53%) of these 64 cases, the HMO paid the bill more than $13,000 in one case either because it had authorized the service or because it believed the beneficiary was not at fault or could not afford to pay.

In another 22% of cases, the physicians who had provided the out-of-plan services went without payment. The unpaid bills totalled more than $26,000 in the case of one 70-year-old man.

* * * *

Mandatory Second Opinions

Medicare might save more than $1 billion a year if patients recommended for nine types of elective surgery were required to seek a second opinion, according to a report from the Senate Aging Committee.

The report, estimated that the nine types of surgery (pacemaker, cataract, gall bladder, prostrate, knee, hysterectomy, back, hernia and hemorrhoidectomy) are performed unnecessarily in 17% to 35% of cases. It projected Medicare savings of $734 to $1.18 billion.

Senate Aging Committee Chairman Sen. John Heinz (R-PA), who released the report at a March 14 hearing, said he may introduce legislation to require second surgical opinions in Medicare and Medicaid. Other committee members, including ranking Ohio Democrat John Glenn, appeared ready to cosponsor such legislation, which Heinz indicated that he may push as a substitute for budget proposals to increase beneficiary cost-sharing.

Heinz is siding with Department of Health and Human Services Inspector General Richard Kusserow in a long-simmering dispute with the Health Care Financing Administration. The dispute traces back to the IG's recommendation in early 1983 that Medicare and Medicaid require second surgical opinions for the nine procedures.

Medicare has paid for voluntary second opinions since 1977 and both the IG and HCFA agree that the voluntary program has had little impact on surgical rates. Both offices also concur that Medicaid programs mandating second opinions for selected procedures appear to have saved money $1 million a year in Massachusetts, for instance.

Both also agree that most savings from the mandated second opinions are not directly due to patient's foregoing surgery but stem instead from the "sentinel effect" in which physicians simply don't recommend certain procedures because they are aware that their decision will be questioned. About 90% of the Massachusetts savings were attributed to the "sentinel effect," for example.

As replayed before the Aging Committee, however, the argument between the two HHS agencies really centers on what mechanism should be used to produce the desired sentinel effect. According to HCFA official James Scott, mandatory second opinions would merely duplicate the efforts of Medicare's new Peer Review Organizations and some state Medicaid review mechanisms. According to Kusserow, the PROs are an inadequate guard against unnecessary surgery because they have no authority to look at outpatient procedures.

A carefully-selected group of witnesses—including a witness from the American Association of Retired Persons and Cornell researcher Eugene McCarthy, M.D., who has long advocated second surgical opinion programs—also called for mandatory Medicare second opinions. They said such programs offer an excuse for patients who fear they will offend their physician if they seek a voluntary second opinion.

Several of the witnesses suggested that physicians do not oppose second surgical opinions as much as their patients believe they do, and Kusserow asserted that mandatory second opinions might protect physicians against malpractice awards.

Medical organizations, including the American Medical Association, have generally supported voluntary second opinions but opposed mandatory plans. Several of the medical groups which had expressed an interest in testifying, however, were permitted only to submit statements after the hearing.

The Aging Committee report also noted that "coronary artery bypass surgery on older men has increased faster than any other type of surgery, rising 1,000% between 1971 and 1978." And several witnesses, including Kusserow, Dr. McCarthy and Harvard researcher and cardiologist Thomas B. Graboys, M.D., suggested that addition of coronary bypass to the list of procedures for which second opinions are required would substantially increase savings.

* * * *

Senate Budget Resolution

A fiscal 1986 budget resolution, which could come up for a Senate vote by mid-April, calls for Medicare cuts of about $3 billion in fiscal 1986 and leaves room for reducing the impact of President Reagan's proposed freeze on Medicare physician fees somewhat. It assumes that all federal funding for health professions education will be eliminated.

The resolution, approved by the Senate Budget Committee in mid-March, still must be approved by the full Senate and any differences with a still-undeveloped House budget resolution resolved. It sets overall spending targets and provides guidance as to how the targets might be met. Congressional authorizing committees must meet the overall target for programs under their jurisdiction, but they are free to ignore the individual spending targets and the budget resolution's recommendations for meeting them.

The Budget panel's resolution includes about a billion less in Medicare savings than the Reagan Administration had proposed. It also lowered the savings anticipated from a physician fee freeze to $310 million in fiscal 1986—as compared with a $500 million savings the President's budget had projected. The lower physician freeze savings stem primarily from the committee's assumption that the freeze will be applied only to M.D.s who did not sign Medicare participating agreements.

The American Medical Association has argued against continuing the Medicare freeze for any physicians unless it was part of a broad freeze on all domestic and defense spending. AMA lobbyists told the Budget Committee members that an extension of the freeze on physician fees would make physician reimbursement the "only area in the budget that would be frozen for two years" and would mean physicians were paid at 1982 levels in 1986.

The final committee plan also differs significantly from the earlier version in that it includes an increase in beneficiary costs. Although the initial proposal had spared beneficiaries entirely, the final measure would increase Part B monthly premiums from the current 25% of costs ($15.50 a month) to 35% of costs (estimated at $34.90) in 1990. Beneficiaries would also be required to pay a new fee for home health visits after the first 20.

The plan also assumes that Medicare rates for hospitals would be frozen in fiscal 1986 and accepts the President's plan to halve payments for indirect medical education costs in 1986. Payments for the direct costs of medical education would be frozen.

For Medicaid, the budget panel opposed the President's proposed freeze on the federal share of benefits. The committee did, however, add a provision that would eliminate the federal contribution to Medicare Part B premiums states pay on behalf of Medicaid beneficiaries. Estimated savings are $300 million in each of the next three years.

The committee's resolution also endorses the Administration's plan to wipe out funds for health planning and health professions assistance in fiscal 1986. In addition, federal funding for guaranteed student loans for all areas of higher education would be reduced by $200 million in 1986. Funding for other discretionary health programs would be frozen and a 5,500 limit would be placed on new biomedical research grants from the National Institutes of Health.

* * * *

Patient Protection Act

The American Medical Association is now warning medical licensing boards of about 40 cases a month in which an M.D. licensed in several states has just been disciplined by one of the jurisdictions, the AMA told Members of the House in March.

The effort, undertaken with the Federation of State Medical Licensure Boards, followed a three-state study by the General Accounting Office that found that 10% of practitioners whose licenses were revoked in one state later billed Medicare or Medicaid for treating patients in another state.

Under current law, Medicare and Medicaid generally can exclude these practitioners only if they are convicted of fraud or abuse against the particular program involved. The GAO recommended that the Department of Health and Human Services be given authority to exclude from participation in federal health programs any practitioner who has been convicted of fraud or abuse in another federal program or whose license had been removed by a state licensing board.

Although the recommendation was supported at the time by the HHS Inspector General as well as by the AMA and other professional groups, differences developed over legislation to implement the recommendation. Swept aside as Congress got tied up in budget bills at the end of the last session, the legislation has now been reintroduced, and as a recent hearing before the House Ways and Means and Commerce health subcommittees revealed, several differences remain.

Called The Medicare and Medicaid Patient and Program Protection Act of 1985 (HR 1370), the measure was introduced by Rep. Henson Moore (R-LA) and cosponsored by many of the members of the two subcommittees. It would authorize the Department of Health and Human Services to exclude from federal health programs any provider who has been convicted of financial, patient or controlled substances abuse; who has lost or surrendered for cause a medical license or the right to participate in any federal program; or who has furnished excessive or poor quality care. An HMO could be excluded for not providing an adequate number of services.

Providers could also be excluded for failing to grant access to records or information about subcontractors or if a civil monetary penalty had been assessed against them. All exclusions would be for a minimum of five years. States would be required to notify a clearinghouse at HHS or an organization designated by HHS of disciplinary actions by state licensing boards.

Although the thrust of the bill is supported by patient representatives, physician groups and the Inspector General, some medical groups believe the legislation now goes beyond the original recommendations of the GAO while senior citizens organizations believe it does not go far enough. Debate has centered on the five year minimum exclusion, the HHS clearinghouse, and the exclusions of physicians or HMOs providing excessive or inadequate numbers of services.

Testifying for the AMA, Board of Trustees member John Ring, M.D., described the Association's use of its physician masterfile to notify the state boards of disciplinary actions against M.D.s licensed in more than one jurisdiction. He also reported that this effort will be expanded to notify the boards whenever the AMA learns of a physician's death.

While endorsing legislation to bar physicians who lose their license for incompetence from Medicare and Medicaid, however, Dr. Ring raised several concerns with HR 1370. The five-year minimum exclusion from federal programs does not give HHS enough discretion to deal with the "various levels of culpability" or fraud that might be encountered, he argued. An HHS clearinghouse of state disciplinary actions would duplicate efforts already taking place, and the authority to exclude providers who deliver excessive or poor quality care has been given and should remain with Peer Review Organizations (PROs).

Defending the minimum five-year exclusion, HHS Inspector General Richard Kusserow asserted that any provider that defrauds Medicare or Medicaid should be excluded from the programs "for as long as the earth spins on its axis."

The most significant difference between HR 1370 and its predecessor in the last Congress involves the addition of authority to exclude HMOs that fail in a substantial number of cases to provide all the services a patient needed. Although Kusserow and General Accounting Office official Michael Zimmerman endorsed this revision, HMO representatives contended that it is unnecessary.

Two groups representing the elderly argued that HR 1370 should be strengthened by requiring rather than permitting exclusion for certain types of fraud or abuse and by requiring public disclosure of state licensing board actions and PRO data.

The two House health subcommittees are also considering a companion bill (HR 1091) introduced by Rep. Ron Wyden (D-OR). Titled the Medical Impostors Act, the bill authorizes HHS to impose civil penalties and seek criminal sanctions against anyone who misrepresents himself as a licensed physician or as a specialist in a field in which he is not certified. The bill drew the wholehearted support of the Inspector General and the qualified support of the AMA after Wyden agreed to work with the Association to clarify that the provision regarding specialty misrepresentation is aimed only at physicians who claim a specialty in an area of medicine for which they are not trained or qualified.

Update: Acquired Immunodeficiency Syndrome—Europe

CENTERS FOR DISEASE CONTROL

As of Dec. 31, 1984, 762 cases of acquired immunodeficiency syndrome (AIDS) have been reported to the World Health Organization (WHO) Collaborating Center on AIDS. During 1984, 417 cases were diagnosed—over half those reported since the disease was first reported and nearly twice the number reported in 1983 (235 cases). The number reported during the last quarter should be considered provisional because of the time lapse between date of diagnosis and notification to the national surveillance centers (Table 1).

For the last six months, the greatest increases in the number of cases were observed in France—80 cases (three per week); Federal Republic of Germany—56 cases (two per week); United Kingdom—54 cases (two per week); Netherlands—21 cases (one per week); and Switzerland—13 cases (one per 2 weeks).

The 15 countries collaborating with the center for the last report[1] have reported 125 new cases, an increase of 11 cases per week.

Two countries, Austria and Belgium, have just joined the center. Austria had reported seven cases at the first European Meeting on AIDS held in Aarhus, Denmark, in October 1983 and now reports 13 cases (six additional cases); Belgium, which had reported 38 cases, now reports 65 cases (27 additional cases).

The highest rates of AIDS cases per million population (1983 populations, Institut National D'Etudes Demographics [INED], Paris) were observed in Belgium and Denmark (seven per million). However, 83% of the Belgian patients (54/65) were Africans, of whom only 18 lived in Belgium before the onset of the first symptoms, in contrast with Denmark, where no African or Caribbean patients have been registered. The rate in Switzerland was six per million; France—five per million; Netherlands—three per million; Federal Republic of Germany and United Kingdom—two per million.

Among the 762 AIDS patients, 376 deaths were reported, for a case-fatality rate of 49% (Table 2). Sixty-one percent of the patients diagnosed one year ago and 83% diagnosed three years ago have died. Sixty-four percent (484/762) of the patients presented with one or more opportunistic infections; 20% (151/762) had

Table 1

REPORTED ACQUIRED IMMUNODEFICIENCY SYNDROME CASES AND ESTIMATED RATES PER MILLION POPULATION—17 EUROPEAN COUNTRIES.*

Country	*October 1983*†	*July 1984*	*October 1984*	*December 1984*	*Rates*§
Austria	7	0	0	13	1.7
Belgium	38	0	0	65	6.6
Czechoslovakia	0	0	0	0	0.0
Denmark	13	28	31	34	6.6
Finland	0	0	4	5	1.0
France	94	180	221	260	4.8
Federal Republic of Germany	42	79	110	135	2.2
Greece	0	2	2	6	0.6
Iceland	0	0	0	0	0.0
Italy	3	8	10	14	0.3
Netherlands	12	21	26	42	2.9
Norway	0	0	4	5	1.2
Poland	0	0	0	0	0.0
Spain	6	14	18	18	0.5
Sweden	4	7	12	16	1.9
Switzerland	17	28	33	41	6.3
United Kingdom	24	54	88	108	1.9
Total	**260**	**421**	**559**	**762**	**2.0**

*Austria, Belgium, Czechoslovakia, Denmark, Finland, Federal Republic of Germany, Greece, Iceland, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, and United Kingdom.

†These data were reported at the 1st European Meeting on AIDS held in Aarhus, Denmark, October 1983.

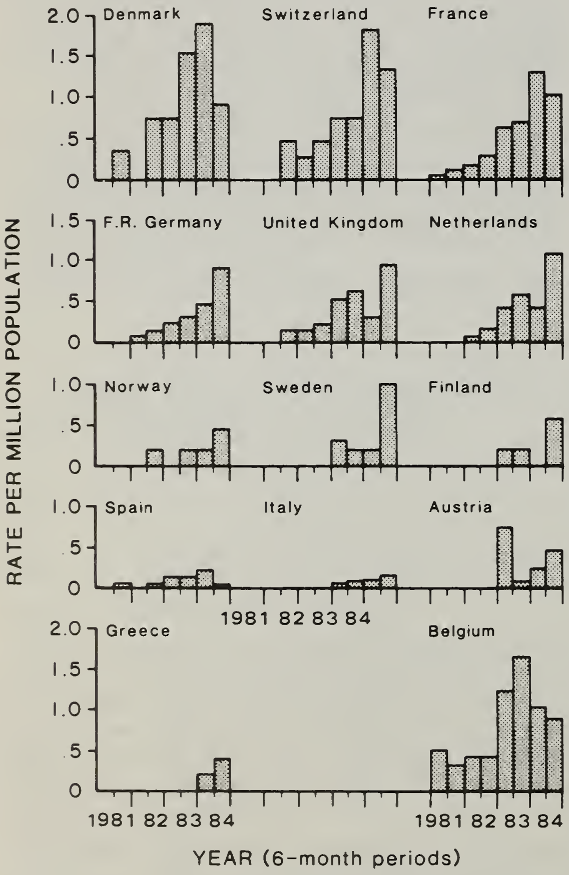
§Based on 1983 populations, INED, Paris.

Kaposi's sarcoma (KS) alone; 16% (121/762) opportunistic infection with KS. The category "others" includes three cases of progressive multifocal leukoencephalitis (France—two; Denmark—one) and three cases of cerebral lymphoma alone (one each in three cases of cerebral lymphoma alone (one each in the Federal Republic of Germany, Switzerland, and the United Kingdom). The case-fatality rate was 67% in the category "others"; 60% for opportunistic infection with KS; 55% for opportunistic infection alone; and 24 for KS alone (Table 2).

Table 2
ACQUIRED IMMUNODEFICIENCY SYNDROME CASES AND NUMBER OF DEATHS, BY DISEASE CATEGORY—17 EUROPEAN COUNTRIES, THROUGH DEC. 31, 1984

Disease category	*Cases (%)*	*Deaths (%)*
Opportunistic infection	484 (64)	264 (55)
Kaposi's sarcoma	151 (20)	36 (24)
Opportunistic infection and Kaposi's sarcoma	121 (16)	72 (60)
Others	6 (*A* 1)	4 (67)
Unknown	0 (0)	0 (0)
Total	762 (100)	376 (49)

INCIDENCE RATES OF ACQUIRED IMMUNODEFICIENCY SYNDROME, BY SIX-MONTH PERIOD OF DIAGNOSIS—14 EUROPEAN COUNTRIES, THROUGH DEC. 31, 1984.*



Ninety-two percent of the patients were men. The sex ratio was 11.7, compared with 15.3 at the last report and can be explained by 20 new cases among women diagnosed in Belgium. Forty-six percent of the patients belonged to the 30- to 39-year age group. The 0- to 1-year age group comprised one boy from Burundi and one from Zaire diagnosed in Belgium; one French girl with a Zairian father, one Haitian boy, and one Zairian boy diagnosed in France. Two children with hemophilia in the 10- to 14-year age group were diagnosed in France. The 15- to 19-year age group comprised two patients with hemophilia (one each in Austria and Spain); one homosexual (France); and one unspecified case (Federal Republic of Germany.)

Cases were geographically distributed as follows (Table 3):

European**—605 cases (79% of total). Five hundred seventy-eight patients lived in Europe before the onset of the first symptoms of AIDS, and 27 (4%) of the 605 patients lived outside Europe (United States—six; Zaire—four; Haiti—three; and one each in Togo, Gabon, Nicaragua, Venezuela, Ghana, South Africa, Burundi, and Bermuda). For six patients, the country of residence was not specified.

Caribbean—24 cases (3%). Twenty-two patients lived in Europe before the onset of the first symptoms: 18 Haitians were diagnosed in France and one in Belgium; one Dominican and one Jamaican lived in the United Kingdom; one of unspecified origin lived in Switzerland. Two other Haitian patients diagnosed in France lived in Haiti.

African—111 cases (15%). In the previous report, 8% of the patients were Africans; the increase is due to the participation of Belgium. These cases were diagnosed in seven European countries and originated from 18 African countries. Sixty-seven percent were from Zaire, and 11%, from the Congo. Among the 16 other countries, the number of cases diagnosed in Europe varied from one to three. This distribution cannot be considered representative of the AIDS situation in Africa. The majority (52%) of these patients lived in Europe before the onset of the first symptoms.

Other origins—22 cases (3%). Most of these patients originated from the American continent: United States—16; one each in Nicaragua, Argentina, Peru, and Canada. One patient originated from Pakistan, and one, from Australia. Thirteen of these patients did not live in Europe before the onset of the first symptoms.

Among the Europeans, 85% (514/605) were homosexual or bisexual (Table 3); 2% (11/605) were drug abusers; and 1% (9/605), both homosexual and drug abusers. The latter 20 cases were diagnosed in the Federal Republic of Germany—nine; Spain—three; France—three; Austria—two; Italy—two; and Switzerland—one.

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*Denmark, Switzerland, France, Federal Republic of Germany, and United Kingdom had cases reported before 1981, which are not included.

**The word European refers to the patients originating from one of the 32 countries belonging to the WHO European region.

Table 3

ACQUIRED IMMUNODEFICIENCY SYNDROME CASES, BY PATIENT RISK GROUP AND GEOGRAPHIC ORIGIN – 17 EUROPEAN COUNTRIES, THROUGH DEC. 31, 1984.

			Nationality		
Patient risk groups	*European*	*Caribbean*	*African*	*Others*	*Total*
1. Male Homosexual or bisexual	514	2	5	16	537
2. Intravenous-drug abuser	11	0	0	0	11
3. Hemophilia patient	20	0	0	0	20
4. Transfusion recipient (without other risk factors)	4	0	4	0	8
5. 1- and 2-associated	9	0	0	2	11
6. No known risk factor					
male	29	17	64	2	112
female	15	4	29	0	48
7. Unknown	3	1	9	2	15
Total	**605**	**24**	**111**	**22**	**762**

Three percent (20/605) were patients with hemophilia. For four of the 605 European patients, the only risk factor found was blood transfusion. For 7% (44/605), no risk factor was found. The information was not obtained for three patients.

Among the Caribbean patients, two of 24 were homosexual; 21 presented no risk factors; for one, the information was not obtained.

The overall presentation of the progress of the AIDS situation in Europe does not take into account the important differences between the countries. Furthermore, the total increase in the number of cases in each country is only of informative value if it is related to the total population of the country. The figure on the previous page shows the variation in the rates per million population per half year for each country where cases have been diagnosed. This figure is difficult to interpret given the qualitative differences in the national surveillance systems. Nevertheless, three situations stand out: for six regions (Denmark, France, the Netherlands, the Federal Republic of Germany, Switzerland, and the United Kingdom) the general trend of these rates shows a constant increase (the data of the second half of 1984 should be considered provisional).

The situation in Belgium is different; stable in 1981 and 1982, it showed an increase in 1983 and a decrease in 1984. This is explained by the arrival of African patients, mainly from Zaire, for treatment in 1983. In 1984, facilities were set up in Zaire for these patients, and hence the decrease in the number of cases in Belgium for that year. Of the 65 cases reported, only seven originated from Belgium. For the third group of countries (Austria, Finland, Greece, Italy, Norway, Spain, and Sweden), the half-year trends do not clearly indicate an increase. If the African cases were excluded, Belgium would come into this group.

Editorial Note

As of Dec. 31, 1984, 17 countries were taking part in the surveillance of AIDS in Europe by reporting their respective data to the center. Since the last report (Oct. 15, 1984),[1] two more countries, Austria and Belgium, have provided data. The center used the CDC case definition. One source per country, recognized by the respective national health authorities, provides the information, and each source is responsible for the quality of the data provided.

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Reported by JB Brunet, MD, Institut de Medecine et D'Epidemiologie Tropicales, Hôpital Claude Bernard (WHO Collaborating Centre on AIDS), Paris, France; Federal Ministry of Health and Environmental Protection, Vienna, Austria; Conseil Superieur de l'Hygiene Publique, Ministere de la Sante, Brussels, Belgium; Institute of Virology, Bratislava, Czechoslovakia; Statens Serum Institute, Copenhagen, Denmark; Institute of Biomedical Sciences, Tampere, Finland; Direction Generale de la Sante, Paris, France; Robert Koch Institute, West Berlin, Federal Republic of Germany; Ministere de la Sante, Athens, Greece; General Direction of Public Health, Reykjavik, Iceland; Instituto Superiore di Sanita, Rome, Italy; Staatstoezicht op de Volksgezondheid, Leidfehendam, Netherlands; National Institute of Public Health, Oslo, Norway; National Institute of Hygiene, Warsaw, Poland; Ministerio de Sanidad y Consumo, Madrid, Spain; National Bacteriological Laboratory, Stockholm, Sweden; Office Federal de la Sante Publique, Berne, Switzerland; Communicable Disease Surveillance Centre, London, United Kingdom.

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Dietary and Pharmacologic Therapy of the Lipid Risk Factors

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Numerous reports over the past 25 years including those of the AMA's former Council on Foods and Nutrition,[1-4] have discussed the relationship between diet and coronary heart disease (CHD). In 1979, a general statement on *AMA Concepts of Nutrition and Health* was adopted by the Council on Scientific Affairs[5] and the House of Delegates (Council Report D, A-79). That statement emphasized that the maintenance of desirable body weight through the combination of dietary control and exercise was a basic step in modifying certain disease patterns. It was also recommended that persons at increased risk of coronary heart disease on the basis of their plasma lipid profiles .... "be given individualized dietary advice based on the type of hyperlipidemia diagnosed and that physicians encourage their patients to achieve or maintain desirable weight."[5]

Risk factors for CHD were reviewed by an American Heart Association (AHA) report through its Steering Committee for Medical and Community Programs.[3] A more recent report entitled "Toward Healthful Diets" by the Food and Nutrition Board of the National Research Council (NRC) Assembly of Life Sciences,[4] challenged current concepts concerning the role of diet in the prevention and treatment of atherosclerotic disease. Subsequently, the Nutrition Committee of the AHA reviewed the literature and presented the rationale for its dietary recommendations.[6] The treatment of hyperlipidemic patients will be discussed in detail in a forthcoming AHA report entitled "Recommendations for the Unified Diet Approach to the Treatment of Hyperlipidemia: Statement for Physicians."[7] In addition, there are multi-institutional cooperative studies now being conducted under NIH sponsorship, such as the Multiple Risk Factor Intervention Trial[8, 9] and the Lipid Research Clinics Program,[10] that are exploring many of the treatment issues discussed here and may soon provide new data on questions of treatment.

Because of differences of opinion regarding the efficacy of dietary and pharmacologic therapy in altering blood lipid concentrations the AMA's Council on Scientific Affairs convened an Advisory Panel of expert consultants in 1981 to review and summarize current knowledge of the treatment of hyperlipidemia and to define the lipid disorders that warrant direct therapeutic intervention by the practicing physician.

The Panel recognized that the physician has an obligation to promote the public health and to be supportive of those measures that he or she believes will reduce risk of atherosclerotic cardiovascular disease, the chief cause of death in the U.S. However, it was charged to address only the treatment of the individual patient who, because of hyperlipidemia, is at significant risk of coronary heart disease.

Background Considerations

For three decades, there has been continuing study of the determinants of atherosclerosis. Epidemiological evidence linking risk factors—such as cigarette smoking, hypertension, hypercholesteremia, diabetes, male sex and advancing age-to incidence of symptomatic coronary artery disease is well established.[3] Several of these risk factors have been shown to be additive; hence atherosclerotic heart disease must be considered to be influenced by a variety of factors. Cessation of cigarette smoking and the control of hypertension have been shown to be of benefit in preventing certain manifestations of atherosclerotic disease. Some data indicate that lowering of the blood lipids, especially the cholesterol, may also be beneficial.

Animal studies have demonstrated that high plasma cholesterol combined with arterial injury are particularly atherogenic. The presence of hypercholesteremia is crit-

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This report is not intended to serve as a standard of medical care: standards of medical care which are determined locally and are constantly subject to change are established on the basis of all the several facts of the individual case.

ical to atheroma formation in most species, and frequently it is the only requirement.

Decreased cholesterol and saturated fat intake in patients under carefully controlled metabolic ward situations without altering energy intake, results in a decrease of perhaps 30% in serum cholesterol concentration. In the more generally applicable circumstances of free-living subjects, the plasma cholesterol decrease is considerably less. On the other hand, in many species, including most of the macaque species of non-human primates, feeding experimental diets containing dietary fats and cholesterol in amounts similar to those in the usual U.S. diet produces a substantial increase in plasma cholesterol levels. The increase in plasma cholesterol can be prevented or counteracted by a diet similar to that recommended by the Inter-Society Commission for Heart Disease Resources.[11] Man is one of those species (more like the baboon, vervet or cebus monkey) whose plasma cholesterol levels are less sensitive to dietary fat and cholesterol manipulations. Whether serum lipid reductions can influence the course of CHD in the human species has not been conclusively established. However, there have been a few clinical trials involving patients with known or suspected CHD in which cardiovascular complications seemed to be favorably influenced by plasma cholesterol reduction.[12-14] Thus, the evidence reinforces the concept that a strong relationship exists between lipid metabolism and atherogenesis.

Cholesterol is transported in the plasma lipoproteins in company with triglyceride (TG), phospholipid and protein. The lipoproteins can be defined by their chemical content, ultracentrifugal flotation, electrophoretic mobility, immunologically defined apoprotein make-up, or microscopic particle size. They are generally classified as high density (HDL), low density (LDL), and very low density (VLDL) lipoproteins and chylomicrons. It has been firmly established that LDL levels correlate directly with the risk of developing CHD. There are also considerable epidemiologic data indicating an inverse relationship between levels of HDL-cholesterol and the incidence of coronary artery disease. It has been suggested that a ratio of total cholesterol: HDL-cholesterol or of LDL-cholesterol: HDL-cholesterol may be an even more precise measure of risk than any single lipid component alone. Continuing efforts to improve the measurement of lipoprotein concentrations and assess their role in atherogensis deserve support.

Present evidence suggests that persons with monogenic familial hypercholesteremia, whether heterozygous (1:500 population) or homozygous (1:1,000,000 population), are deficient in the number or function of cellular LDL membrane receptors and exhibit enhanced incorporation of acetate into cholesterol by their skin fibroblasts and other cell lines.[15] Thus, in familial hypercholesteremia the receptor defect impairs the clearance of LDL from the plasma and appears to result in an increased cholesterol synthesis so that the degree to which it is correctable by either dietary or pharmacologic means may be limited.

Although plasma TG also shows a correlation with cardiovascular risk, an independent association remains doubtful. The reported association is largely explained by the fact that the VLDL, which carries most of the endogenous triglyceride of the plasma, is a metabolic precursor of LDL and its level in the plasma varies inversely with that of HDL.[15]

Plasma Lipid Measurement

Because of biologic variation and laboratory imprecision of plasma cholesterol and TG determinations, most research studies require a mean of three determinations to be made at intervals of one or more weeks to establish a baseline value; for clinical practice two determinations should be adequate. Ideally, the blood lipids should be measured as individuals reach adulthood, since accelerated atherogenesis occurs between 20 to 40 years of age. In families in which familial hypercholesteremia has been documented, blood lipids should be determined in childhood, or even infancy, since this disorder can be recognized in affected offspring early in life.

Plasma cholesterol exhibits relatively little diurnal variation; triglyceride levels increase markedly after ingestion of any fat. Reference standards for TG usually are based on determinations after a 12 or 14 hour overnight fast. Triglycerides not exceeding the limits of normal on a casually drawn blood sample may be acceptable, but, if elevated, a fasting specimen should be obtained for confirmation.

The standard chemical determination for plasma cholesterol, the Abell-Kendall (A-K) technique, involves the Liebermann-Burchard reaction after hydrolysis and extraction of the cholesterol. In the hands of the Core Laboratories of the North American Lipid Research Clinics, the Auto Analyzer II gave results that agreed very closely with the A-K reference method, but use of a serum calibrator was required.[16]

The Auto Analyzer II also determined plasma triglyceride with a mean error of less than 5% from a reference value.[17] These automated methods, as well as some of the newer, more convenient enzymatic techniques, can all give satisfactory results, but only if the laboratory is rigidly standardized. Although less rigorous methods may be suitable for screening purposes, accuracy and precision in the laboratory are very important for monitoring therapy.

A survey by the Centers for Disease Control of clinical laboratories performing HDL-cholesterol determinations found that over half of the laboratories deviated from the test sample by more than 7.5%. This suggests that in the range of 30-40 mg/dl, which is the high risk zone for HDL-cholesterol determination, laboratory precision is inadequate in the majority of laboratories. A wide within-laboratory variation reported by some laboratories suggested poor analytical technique. Thus, in those instances where lipid values are particularly high or unresponsive to therapy, and lipoprotein studies are warranted, the physician should be assured of his laboratory's quality control for these determinations.

Defining Hyperlipidemia

Optimal Blood Lipid Levels

In deciding what levels of plasma cholesterol or TG should be considered as normal, the panel felt that population data must be evaluated to determine the "optimal level" of blood lipids. *There is good reason to believe that the average cholesterol levels in individuals in the US may be higher than optimal due in part to the typical US diet.* On the other hand, some recent studies have shown an increased incidence of malignancies in sample populations with levels of plasma cholesterol less than 180 mg/dl.[18] Even though some reports regarding colon cancer contradict this general finding, it is possible that plasma cholesterol levels may correlate with different diseases at the upper and lower extremes of cholesterol distribution in western populations. The desirable level should be compatible with optimal growth and development and yet minimize the risk of premature disease. Adults in primitive and oriental societies have a mean total plasma cholesterol between 150-200 mg/dl.[6] Mean total plasma cholesterol values of 140-180 mg/dl in such populations were found to be consistently related to the lowest rates of atherosclerosis and coronary heart disease (CHD).

As the mean total plasma cholesterol of populations rises above 200 mg/dl the incidence of CHD increases proportionately. Thus, average total plasma cholesterol levels of 180-200 mg/dl in adult populations seem to be associated with a low incidence of both cardiovascular and other diseases and probably should be considered optimal.

Hyperlipidemia

It has been demonstrated in many population studies that cardiovascular risk—measured as myocardial infarctions or coronary deaths—varies directly with mean plasma cholesterol level. In the National Cooperative Pooling Project, when the healthy 40 to 64-year-old men under study were divided into fifths (quintiles) according to their plasma cholesterol level, the upper fifth had a primary attack rate per ten years (324 per 1,000) about twice that (163) in the lowest two fifths.[19] The intervening quintiles, 3 and 4, showed a linear gradation in risk. This means that even at the median level of plasma cholesterol a further decrease in cholesterol level may bring about a further reduction in cardiovascular risk. Concentrating, for example, on treating only those above the 80th percentile would ignore the majority of people who may be at an increased risk of future heart attacks. Thus, the arbitrary decision that is usually made, to consider the normal range of a biological parameter to be between the 5th and 95th percentile, is not appropriate in setting the criteria for treatment of this correlate to the primary cause of death in the middle-aged American male.

In the US white population there is a definite association between age and total plasma cholesterol level that is different in the two sexes. The Lipid Research Clinics Program recently surveyed 12,595 Americans in order to provide contemporary data on the distribution of the plasma lipid parameters in men and women 20 to 79 years of age in the US and Canada. The accompanying Table 1 presents the resulting values for age and sex of cholesterol, triglyceride, LDL-cholesterol, and HDL-cholesterol.[10, 17]

Table 1

50TH and 90TH PERCENTILES FOR PLASMA LIPID CONCENTRATION mg/dl†

	MEN				WOMEN			
	Total Cholesterol		*Triglycerides*		*Total Cholesterol*		*Triglycerides*	
	Percentile				*Percentile*			
Age	*50th*	*90th*	*50th*	*90th*	*50th*	*90th*	*50th*	*90th*
20-29	172	215	90	182	164	207	65	114
30-39	194	234	109	232	176	219	71	130
40-49	206	254	123	250	195	241	84	163
50-59	211	261	122	242	222	275	111	194
60-69	210	258	116	222	228	280	108	203
70-79	205	249	112	212	228	280	110	200

50TH AND CRITICAL PERCENTILES FOR LDL AND HDL CHOLESTEROL mg/dl*

	MEN		WOMEN		MEN		WOMEN	
	HDL-CHOLESTEROL				*LDL-CHOLESTEROL*			
	Percentile				*Percentile*			
Age, Year	*50th*	*90th*	*50th*	*90th*	*50th*	*10th*	*50th*	*10th*
20-29	208	147	100	138	45	32	52	38
30-39	128	171	113	151	44	32	54	39
40-49	138	180	124	168	44	32	56	39
50-59	144	188	144	196	45	31	58	40

†From the Lipid Research Clinic Data: Reference 10.
*From the Lipid Research Clinic Data: Reference 17.

The panel agrees with the proposal of the American Heart Associations' Steering Committee that the 90th percentile for a patient's age and sex, according to this US population data, should be defined as the lower limit for an "overt hypercholesteremia."[7] The 50th percentile, since it approximates the upper limits of the optimal range described above, may also provide a convenient reference point.

The Decision to Treat

The decision to treat an elevation of plasma cholesterol or triglyceride must be individualized. It depends not only upon the patient's age and sex but upon many other personal characteristics, as well as the specific plasma lipoprotein pattern. Furthermore, the reduction of plasma lipids to reduce the risk for coronary heart disease should be regarded by both physician and patient as only one part of a comprehensive health program directed at all applicable risk factors.

In many instances hyperlipoproteinemia is associated with diabetes mellitus, hypothyroidism, nephrosis, obesity, excessive alcohol consumption, the use of contraceptive pills, biliary obstruction or other genetic hyperlipidemias. Treatment of the primary condition may preclude the necessity for strenuous dietary or drug therapy. The rare genetic causes of hypertriglyceridemia, such as the hereditary lipoprotein lipase deficiency and the dysbetalipoproteinemia characterized by the presence of floating beta lipoproteins that appear in the VLDL partition of serum lipoproteins, deserve mention. The former is treated by restricting all dietary fat to less than 50 gm per day; some investigators suggest 25 to 30 gms per day. The latter is treated the same as essential hypertriglyceridemia with VLDL elevation discussed later in the report.[15]

It should be appreciated that the reduction of plasma cholesterol attained by dietary means in the free-living subjects of the Diet Heart Feasibility Study[20] averaged only 10% to 12%; in the Multiple Risk Factor Intervention Trial, started ten years later, it was only 6.5%, in spite of special attention to patient motivation and dietary instruction. Thus, while a few patients may achieve a substantial plasma cholesterol reduction in response to diet, many will achieve only slight improvement. For many, especially those patients with familial hypercholesteremia, drug therapy may be required in addition to diet therapy.

It is not yet clear whether the treatment of the hereditary (familial) hypercholesteremia or hypertriglyceridemia should be any different than that of the environmental or sporadic types described above. It is generally conceded that the hereditary hyperlipidemias are less responsive to treatment by either diet or drug therapy than are the environmental types even though the need for treatment is more compelling. Because of the resistance to simpler treatment, some investigators have advocated more radical steps, such as plasmapheresis or partial ileal-bypass surgery, in some instances. Such investigational treatments are not the subject of this report and will not be considered further.

The first step in any therapy of a primary elevation of blood lipids, after excluding other disorders known to cause hyperlipoproteinemia, is to attain and then maintain a desirable body weight. This goal can be facilitated by the use of a fat modified diet and should be pursued as further specific measures are undertaken to reduce elevated plasma lipoprotein levels. Diet therapy is generally safer than and, when successful, may preclude drug treatment. Diet therapy should always be attempted first and the effort should continue throughout the pursuit of drug therapy.

The Council on Scientific Affairs' Advisory Panel recommends that any person under age 60 with "overt hypercholesteremia," as defined by the 90th percentile for his or her age and sex, deserves dietary treatment and, if this is not successful, drug therapy. It further believes that any person with a plasma cholesterol above the median (50th percentile) would benefit from cholesterol reduction (and weight control if needed) by a diet low in cholesterol and saturated fats accompanied by some increase in polyunsaturated fats.

The panel also agrees that the decision to treat those patients between the 50th and 90th percentile is with the recommended diet is a clinical decision that should rest with the patient and his or her physician. The decision whether to treat and the intensity of the treatment should depend upon many variables including present dietary pattern, age, family history, cardiovascular risk profile, accompanying disease, disability, prognosis and the compliance with or adverse effects of the treatment regimen.

Although there is little evidence to suggest that older patients stand to benefit as much from diet therapy as those under 60 years, the Panel believes that older patients deserve the same care and consideration as younger ones. Most of the studies relating disease to plasma lipid levels have been confined to the younger (under 65) age group. Many of the correlations between the plasma lipids and CHD are lost after 60 to 65 years of age, but the LDL/HDL ratio still exhibits relationship after age 60. The reversibility of lesions is, perhaps, less likely with advanced age. On the other hand, it can be argued that, because the atherosclerosis may be more advanced and the arterial intima more abnormal, there is all the more reason to obtain whatever benefit may be achieved from lowering the plasma cholesterol. In fact, in several experimental studies, endothelial healing appears to be one of the first results of lowering the plasma cholesterol.

Diet Therapy

The American Heart Association Diet

A diet that has been demonstrated to effectively lower the plasma cholesterol of institutionalized patients is one that is moderately low in total fat, particularly in saturated fats, and low in cholesterol content, but adequate in protein. The diet for the management of hypercholesteremia that has been proposed by the AHA includes a daily intake of no more than 300 mg of cholesterol; no more than 30%-35% of calories as fat, (only 10% derived from saturated animal fats and 10% or more derived from fats and oils rich in polyunsaturated fatty acids).[3] In heterozygous familial hypercholesteremia, this type of diet will, under controlled conditions, usually reduce the plasma cholesterol by 10%-15%, but not enough to restore serum cholesterol to "normal." In other patients, whose hypercholesteremia may be of dietary origin, strict adherence to such a diet may induce substantial reductions in plasma cholesterol levels, particularly in the LDL fraction.

Decreasing saturated fats in the diet and increasing polyunsaturated vegetable oils will generally reduce plasma cholesterol levels. However, it should be appreciated that some vegetable oils are more effective in this regard than others and the effect depends upon whether they replace saturated fats or carbohydrates. Salad oils such as corn, safflower, cottonseed and soy bean are high in polyunsaturated fatty acids and will lower the plasma cholesterol when substituted for carbohydrates. Substitution of the predominantly monounsaturated olive oil in place of carbohydrates has little effect, but if it is substituted for saturated fat, it has a lowering effect. Coconut and palm oil, both rich in saturated fatty acids, when substituted for carbohydrates tend to raise the plasma cholesterol levels. When included as a large element of the experimental diet, peanut oil seems to potentiate the formation of experimental atheromata in animals. The proportion of polyunsaturated fat in the diet, relative to saturated and monounsaturated fats, is important in selecting dietary fats.

In the recently published steering committee report from the AHA,[7] a phased approach to dietary management is recommended. The above diet recommendation is only considered Phase I. In Phase II, recommended for unresponsive or severe cases, the fat and cholesterol intake should not exceed 30% of calories and 250 mg per day, respectively. If satisfactory reduction of cholesterol is not accomplished in either the first or second phase, a Phase III is recommended that is similar to that required for the treatment of familial lipoprotein lipase deficiency. This is a more restricted diet containing only 20%-25% of calories as fat, with less than 10% from saturated fat, and less than 100 mg of cholesterol per day. Some investigators believe that this type of rigid dietary control, if implemented early and continued for a lifetime, will suffice to correct the plasma abnormality in heterozygous familial hypercholesteremia. However, others have concluded that only a few people can be persuaded to follow such a stringent diet for a lifetime; drug therapy may be necessary or even preferable, even though the effects of life-long drug therapy are not known.

The more modest recommendations for Phase I are not difficult to follow even for a protracted period of time. The AHA Steering Committee believes, that this diet can be recommended for any individual whose serum cholesterol level is above the 50th percentile. The dietary specifications for Phase II can be met by palatable Mediterranean or Oriental diets, which have been staple diets for large population groups for many generations. Although such diets have not yet been used widely enough in the US to assess long-term compliance, they are certainly gastronomically acceptable.

In practical terms, this means that the patient should be instructed to limit the intake of all animal fats derived from meat and dairy products and to utilize vegetable oils whenever possible. To achieve the Phase III diet recommendations and still maintain a nutritionally adequate diet, the assistance of a dietician will be helpful.

Diet and Hypertriglyceridemia

Elevated plasma TG, may also require treatment if only because correcting the hypertriglyceridemia will usually reduce the plasma cholesterol as well. Many patients who have increased plasma triglycerides due to elevations of VLDL are late-onset diabetic subjects. It has recently been shown that adequate treatment of the diabetes may lower the plasma triglycerides and the plasma cholesterol in such subjects. The remaining hypertriglyceridemic patients, in whom there is no glucose intolerance and no relation to drug intake or disease process, may be helped by calorie restriction and the above Phase I diet. Sometimes, such patients will show dramatic increase in serum triglycerides with a high carbohydrate diet, but this will usually subside in several weeks to months as the diet is continued (endogenous carbohydrate-induced hyperlipidemia). A similar reaction can be seen in response to alcoholic beverages; for this reason, alcoholic beverages are generally proscribed. If the plasma TG remains above the 90th percentile in spite of abstinence from alcohol and weight reduction, it may be necessary to restrict carbohydrate intake. Drug therapy has also been recommended.[15] However, no drug is free of risk and there is little evidence that reduction of an isolated hypertriglyceridemia, in the absence of high LDL or low HDL, will indeed reduce cardiovascular risk.

Role of the Patient

The role of the patient in management of the hyperlipidemia cannot be overemphasized. Compliance with dietary instructions and, if needed, with drug schedules, is crucial. Experience with poor adherence in the management of usually asymptomatic disorders such as hypertension, obesity, and hypercholesteremia indicates the difficulties encountered in gaining compliance. Further investigation of behavioral factors that may influence adherence to such diet and drug regimens is needed.

One aid to reinforcement of the dietary program is family involvement. Because of the familial nature of many hyperlipidemias and because dietary management is a family affair, a good case can be made for extending dietary recommendations to the entire family of the patient.

Drug Therapy

The drug treatment of patients with hyperlipidemia has been discussed in the publication *AMA Drug Evaluations.*[21] Insights into apolipoprotein influences on lipid transport have helped to clarify the action of lipid-lowering drugs. Bile acid sequestrants appear to enhance apolipoprotein B catabolism. Nicotinic acid decreases LDL and VLDL synthesis and clofibrate accelerates VLDL catabolism. Further study of the metabolism, structure and functions of the apoproteins should more precisely define the underlying metabolic defects and clarify the mode of action of hypolipidemic drugs. Thus, drug therapy that is effective in dealing with an increased level of VLDL may not be appropriate for an increased level of LDL in the serum. In fact, the reduction of the LDL level through the use of an exchange resin may lead to an increased VLDL, level in certain individuals. As the treatment of different hyperlipoproteinemias involves different mechanisms and different pharmacologic actions, it is reasonable to consider a combined drug regimen in stubborn cases.

Because any drug regimen may have undesirable side-effects in some patients and because treatment must be pursued for a lifetime if risk factor reduction is to be maintained, drugs are not recommended except in patients whose lipids remain abnormal in spite of an adequate trial of diet therapy and weight reduction. The Council on Scientific Affairs' Advisory Panel recommends drug therapy in those high-risk patients under 60 years of age, especially those with CHD, who have a sustained elevation of plasma cholesterol above the 90th percentile after a three to six month trial of diet modification. The safety and efficacy of various lipid lowering drugs is under intense investigation, and no single drug has yet been unequivocally proven capable of reducing the likelihood of new cardiovascular events. Nevertheless, there is a rationale for pharmacological correction of risk factors in this high risk group.

Patients with familial hypercholesteremia and those with serum cholesterol elevations of environmental origin can be treated with cholestyramine (Questran^R) in a dose of 12-16 gms of the base, or colestipol resin (Colestid^R) in an amount of 15-30 gm per day. The addition of one of these drugs to good dietary management may further reduce the LDL-cholesterol level by 15% to 30%. While this remains the treatment of choice at present for hypercholesteremia, its primary disadvantage relates to gastrointestinal symptoms that discourage many patients from pursuing the drug therapy for any protracted period of time. Other regimens that have been used are generally not as effective and are more prone to side effects that may preclude long term use: these include neomycin sulfate, probucol (Lorelco^R) and, in patients with no known heart disease, dextrothyroxin sodium (Choloxin^R).

Although neomycin has been recommended (0.5 gm tablet, 3 or 4 times/day), it yet lacks FDA labelling as being indicated in hypercholesteremia. It is a broad spectrum aminoglycoside antibiotic that is poorly absorbed from the intestinal tract. It lowers plasma cholesterol levels at very low doses compared to that used to sterilize the large bowel, by enhancing the fecal excretion of neutral sterols. About one-third of the time it induces an initial diarrhea which subsides in 1 to 2 weeks and is easily controlled by Lomotil. At these low levels of drug administration there are few other systemic side-effects, as long as renal function is normal. In effectiveness and cost, this drug compares favorably with probucol and the rationale for its use is better understood.

Probucol (Lorelco^R) (two 250 mg tablets b.i.d.) has also been recommended for lowering plasma LDL and cholesterol levels. Although this seems to be well tolerated except for occasional mild gastrointestinal complaints, the long-term effects of this drug are not yet well defined, and it also reduces HDL levels. It seems to be better tolerated than cholestyramine, although its relative effectiveness has not been compared to resin treatment.

Nicotinic acid (Nicolar^R) in doses of 3 to 12, 500 mg tablets daily will also lower the plasma LDL level some 15% to 30% and it is also effective in the reduction of VLDL levels. It increases HDL levels. It is the drug of choice for those patients who have VLDL or combined elevations. Its chief side-effect is flushing, but gastrointestinal symptoms may also occur and some increase in serum uric acid and glucose levels is reported.

Dextrothyroxine sodium (Choloxin^R) in doses of 4 to 6 mg per day has been shown to reduce total plasma cholesterol and LDL cholesterol by 20% in most patients by enhancing apolipoprotein B catabolism. It also has calorigenic effecs and is best avoided in patients with heart disease because of its capacity to induce or enhance angina pectoris and certain arrhythmias. It remains an acceptable treatment in young hypercholesteremic subjects without heart disease.

Clofibrate (Atromid-S) (500 mg 3 or 4 times/day) has been used chiefly for hyperlipidemias in which triglycerides are elevated. Because of a greater effect on VLDL than LDL, more modest effects on plasma cholesterol are induced. Both decreased VLDL production and especially increased clearance have been postulated to occur. Clofibrate increases lipoprotein lipase and promotes clearance of VLDL triglycerides. It also causes an increased intestinal cholesterol excretion in association with a high secretion of cholesterol into the bile. Enhanced saturation of gallbladder bile with cholesterol does increase the risk of gallstones.

The recently approved gemfibrozil (2 opid) also has a primary effect upon VLDL in doses of 600 mg twice daily. It has many actions similar to Clofibrate, but experience with it has been much less extensive so that the mechanism of action is less well understood and the adverse reactions less well defined at this time.

In the treatment of VLDL elevations, clofibrate and niacin both seem to be effective. Niacin induces cutaneous flushing during its early stages of administration; this can be troublesome and led to a poor compliance in 15% of patients in the Coronary Drug Project.[22] In that experience, niacin produced a greater fall in plasma cholesterol levels than did clofibrate and this was sustained for a 5-year period of follow-up. There was a concommitant reduction in plasma triglycerides, and, while both fatal and non-fatal myocardial infarctions were slightly less than in a placebo group over the 5-year period, only the latter difference was statistically significant. Clofibrate in two large scale trials[22,23] was associated with an increased incidence of gallstones and, in one, with a statistically insignificant increase in certain malignancies when compared with the effects of a placebo.[22] Deaths from all causes were significantly higher in those receiving clofibrate than in the controls. It is largely because of this experience that nicotinic acid has superseded clofibrate as the drug of choice in the management of increased levels of both LDL and VLDL in the plasma.

In those patients who have a persistent elevation of LDL and/or VLDL, even after full compliance with dietary restrictions and one of the above drug schedules, it may be worthwhile to resort to combined drug therapy. The combinations that have proved efficacious in selected cases are a resin plus niacin or probucol.

Recommendations

Through the Council on Scientific Affairs, the Advisory Panel makes the following recommendations:

1. Initial search for the presence of hyperlipidemia ideally should be done at or before age 20.
2. Prior to initiating treatment, fasting levels of plasma cholesterol and triglyceride should be measured at least twice, to determine a base-line value. Full lipoprotein profiles are not ordinarily necessary before initiation of therapy.
3. Underlying disorders (e.g., alcoholism, diabetes, hypothyroidism, etc.) known to cause elevation of plasma lipoproteins should be identified and treated directly when present.
4. Vigorous dietary therapy should be initiated in patients who have mean serum cholesterol levels above the 90th percentile for age and sex. Patients less than 60 years of age and who continue to have plasma lipid elevations unresponsive to dietary therapy deserve a trial of long-term drug therapy.
5. Patients with plasma lipid levels in the range of the 50th to 90th percentile for age and sex may also benefit from diet therapy, because the majority of CHD patients emerge from this group. Factors such as age, sex, family history, other risk factors, accompanying disease, prognosis and anticipated compliance may all influence the clinical decision to treat the hyperlipidemia.
6. Diet therapy of hypercholesteremia and hypertriglyceridemia should include instruction in attaining and maintaining a desirable body weight. Further measures include a diet which contains no more than 30% to 35% of calories as fat, less than 10% of calories from sources of saturated fat and at least 10% of calories from oils rich in polyunsaturated fatty acids. There should be less than 300 mg/day of cholesterol with an adequate protein intake.
7. In patients who have not reached an optimal level of plasma cholesterol on the above diet, further restriction of fat to less than 30% of calories and cholesterol to less than 250 mg/day may be warranted.
8. If the plasma triglyceride level remains above the 90th percentile, alcohol should be proscribed and carbohydrate restriction may be necessary. Drug therapy is not usually justified in an isolated hypertriglyceridemia.
9. Because one family member with hyperlipidemia suggests that other members may be at risk, and because dietary management is a family affair, consideration should be given to extending the dietary recommendations to the patient's entire family.
10. Control of plasma lipid levels is only one facet in cardiovascular risk management. Other factors such as cessation of cigarette smoking, blood pressure control and the medical management of glucose intolerance must not be ignored.

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Letters to the Editor

RAST REVISITED

To the Editor: The recent article ("Epitomes of Progress—Allergy," Feb., 1985, Pg. 89), summarizing advances in allergy included a description of the Radioallergosorbent Test known as RAST. In general, the report is much more factual and positive than some of the writings on this subject, published in recent years. When RAST was introduced into this country some ten years ago, its acceptance was slow because of initial cost factors involved as well as the question of its sensitivity and specificity. As with any phase in medical progress, there is a tendency to frequently allude to the early shortcomings and to minimize the advances which have occurred. It is true that the skin testing, as developed seventy-five years ago, is time honored and is used by the vast majority of the practicing allergists. However, more recently there has been a grudging acceptance by some allergists that there is something of value on the other side of the wall that has surrounded them.

Cost factors are very important to the major insurance carriers as well as government health agencies. The development of the Rast Screen approach has dramatically decreased the expense of this in-vitro procedure. It has also served to reduce the overall cost of allergy care, since it has eliminated the probability of treatment based on the conventional methods of skin testing in many instances. The RAST may be used in allergy treatment by some physicians with inadequate training or knowledge of the atopic patient. Similarly, many ill-trained physicians have been using the widely advertised skin test and treatment sets for a number of years. It is quite possible that such physicians will now turn to in-vitro tests such as RAST. The probability, however, is that the conscientious family practice physician internist and pediatrician will now utilize the Rast Screen, as they now use other profiles in evaluating their patients. They will then be in better position to refer the patient in a much more rational and economical manner to the appropriate allergist, when the history and screen indicate such a need.

Timothy L. Curran, M.D.

Hartford, CT

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Drugs for Hypertension

THE MEDICAL LETTER

About 20% of adults in North America have arterial blood pressures consistently above the normal range. Nondrug therapy, such as weight reduction, exercise, and dietary sodium restriction, may have a modest therapeutic effect on high blood pressure, but most patients with hypertension require treatment with drugs (Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, Arch Intern Med, 144:1045, 1984). Drugs available in the USA for treatment of chronic hypertension are listed on pages 330 and 331. (Drugs used to treat hypertensive crisis will be discussed in future issues of *The Medical Letter.*

Diuretics

Many **thiazide-type diuretics** are used to treat hypertension; although dosage and duration of action vary, all have similar effects, except that metolazone *(Zaroxolyn; Diulo)* may be effective in patients with impaired renal function when thiazides are not. In addition to being used alone, thiazide-type diuretics can add to the effectiveness of other antihypertensive drugs and reverse the fluid retention that occurs with some of them. Diuretic doses higher than 50 mg of hydrochlorothiazide *(Esidrix;* and others) or its equivalent rarely add to the effect on blood pressure and can worsen adverse metabolic effects. Hyperuricemia, hyperglycemia, and hypokalemia are common complications. Alternatives to thiazide-type diuretics should be considered for patients with electrocardiographic abnormalities (NM Kaplan, Am J Cardiol, 51:1786, 1983). Nonsteroidal anti-inflammatory drugs, including ibuprofen *(Motrin; Rufen; Nuprin, Advil),* which is now available without a prescription, can decrease the diuretic and antihypertensive effects of thiazide-type diuretics.

The diuretic **furosemide** *(Lasix;* and others) has a shorter duration of action than thiazide-type diuretics and may be less effective for treatment of hypertension. Use of furosemide in hypertension should be reserved for patients with fluid retention that cannot be controlled with thiazides or for patients with impaired renal function; since it has a different site of action, furosemide may be effective for such patients when thiazides are not.

Three potassium-retaining diuretics are available. These drugs are used mainly in combination with other diuretics to prevent or correct hypokalemia. They do not cause hyperuricemia or hyperglycemia, but hyperkalemia is a potentially life-threatening adverse effect in patients with renal impairment; serum potassium concentrations must be monitored, particularly in diabetics, the elderly, patients with renal failure and those receiving other drugs that can lower aldosterone secretion, such as captopril *(Capoten)* or nonsteroidal anti-inflammatory drugs. **Amiloride** *(Midamor)* is a potassium-retaining diuretic with antihypertensive effects that can add to those of the thiazides (Medical Letter, 23:109, 1981). The aldosterone antagonist **spironolactone** *(Aldactone)* also has antihypertensive activity, but causes more troublesome adverse effects, particularly tender gynecomastia in men. **Triamterene** *(Dyrenium),* also a potassium-sparing diuretic, is not an effective antihypertensive agent when used alone.

Drugs with Peripheral Sympatholytic Action

Beta-adrenergic blocking drugs are effective for treatment of hypertension and are usually well tolerated. In blacks, however, beta-blockers are less effective than thiazide diuretics; in whites, the two types of drugs are about equally effective for initial treatment (VA Cooperative Study Group, JAMA, 248:1996, 1982). All beta-blockers appear to be equally effective for treatment of hypertension, and any can be used alone as initial therapy. As with other antihypertensive drugs, however, diuretics can add to the effectiveness of the beta-adrenergic blockers. All of the beta-adrenergic blocking drugs can aggravate congestive heart failure, and they should not be used to treat hypertensive patients with asthma or obstructive pulmonary disease. When used as initial therapy, the incidence of adverse effects requiring withdrawal of beta-blockers is similar to that of the thiazides (Medical Research Council, Lancet, 2:539, 1981).

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SOME ORAL ANTIHYPERTENSIVE DRUGS

Drugs	*Daily Adult Dosage*	*Frequent or Severe Adverse Effects**
DIURETICS		
Thiazide-type		
Chlorothiazide *(Diuril;* others)	250 mg to 1 gram in 1 or 2 doses	
Hydrochlorothiazide *(Esidrix;* others)	25 to 50 mg in 1 or 2 doses	
Benzthiazide *(Exna;* others)	25 to 200 mg in 2 to 4 doses	
Hydroflumethiazide *(Saluron; Diucardin)*	25 to 100 mg in 1 or 2 doses	
Bendroflumethiazide *(Naturetin)*	2.5 to 20 mg in 1 dose	Hyperuricemia; hypokalemia; hypomagnesemia; hyperglycemia; hyponatremia; hypercalcemia; pancreatitis; rashes and other allergic reactions; increased serum lipid concentrations
Cyclothiazide *(Anhydron)*	1 to 6 mg in 1 to 3 doses	
Methyclothiazide *(Enduron; Aquatensen)*	2.5 to 5 mg in 1 dose	
Trichlormethiazide *(Naquá;* others)	2 to 4 mg in 1 dose	
Polythiazide *(Renese)*	2 to 4 mg in 1 dose	
Quinethazone *(Hydromox)*	50 to 200 mg in 1 or 2 doses	
Chlorthalidone *(Hygroton)*	25 to 50 mg in 1 dose	
Metolazone *(Zaroxolyn; Diulo)*	2.5 to 5 mg in 1 dose	
Indapamide *(Lozol)*	2.5 mg in 1 dose	
Loop Diuretics		
Furosemide *(Lasix;* and others)	80 to 320 mg in 2 to 3 doses	Dehydration; circulatory collapse; thromboembolism; hypokalemia; hypomagnesemia; hypocalcemia; hyperglycemia; metabolic alkalosis; hyperuricemia; blood dyscrasias; rashes
Bumetanide *(Bumex)*	0.5 to 10 mg in 2 to 3 doses	
Potassium-retaining		
Amiloride *(Midamor)*	5 to 10 mg in 1 dose	Hyperkalemia; GI disturbances; rash; headache
Spironolactone *(Aldactone;* others)	50 to 100 mg in 1 or 2 doses	Hyperkalemia; hyponatremia; gynecomastia; menstrual abnormalities; GI disturbances; rash; tumorigenic in rats
Triamterene *(Dyrenium)*	50 to 200 mg in 2 doses	Hyperkalemia; GI disturbances; increased blood urea nitrogen; metabolic acidosis, nephrolithiasis
Some Combinations		
Dyazide (hydrochlorothiazide 25 mg and triamterene 50 mg)	1 or 2 bid	
Maxzide (hydrochlorothiazide 50 mg and triamterene 75 mg)	1 daily	
Aldactazide (hydrochlorothiazide 25 mg and spironolactone 25 mg)	2 to 4 daily	
Moduretic (hydrochlorothiazide 50 mg and amiloride 5 mg)	1 or 2 daily	
DRUGS WITH PERIPHERAL SYMPATHOLYTIC ACTION		
Beta-adrenergic blocking drugs		
Propranolol *(Inderal)*	Initial: 40-160 mg in 2 doses Maintenance: 120 to 320 mg in 2 doses	Fatigue; bradycardia; decreased exercise tolerance; congestive heart failure; GI disturbances; increased airway resistance; Raynaud's phenomenon; vivid dreams or hallucinations; organic brain syndrome; rare blood dyscrasias and other allergic disorders; sudden withdrawal can be dangerous
Nadolol *(Corgard)*	Initial: 20 mg in 1 dose Maintenance: 80 to 160 mg in 1 dose	Similar to propranolol; no data on withdrawal
Timolol *(Blocadren)*	10-20 mg in 2 doses	Similar to propranolol
Metoprolol *(Lopressor)*	Initial: 50 mg in 1 or 2 doses Maintenance: 100 to 200 mg in 1 or 2 doses	Similar to propranolol; at doses <200 mg is relatively cardioselective
Atenolol *(Tenormin)*	25 to 100 mg in 1 dose	Similar to propranolol; relatively cardioselective at ≤100 mg/d
Pindolol *(Visken)*	10 to 40 mg in 2 doses	Less resting bradycardia, otherwise similar to propranolol
Labetalol *(Trandate, Normodyne)*	200-1200 mg in 2 doses	Similar to propranolol but more orthostatic hypotension

DRUGS WITH PERIPHERAL SYMPATHOLYTIC ACTION (continued)		
Beta-adrenergic blocking drugs		
Reserpine *(Serpasil;* others)	0.05-0.25 mg in 1 dose	Psychic depression; nightmares; nasal stuffiness; drowsiness; GI disturbances; bradycardia
Guanethidine *(Ismelin)*	10-300 mg in 1 dose	Orthostatic hypotension; diarrhea; may aggravate bronchial asthma; bradycardia; sodium and water retention
Guanadrel *(Hylorel)*	10-50 mg in 2 doses	Similar to guanethidine, but aggravation of asthma has not been reported
Prazosin *(Minipress)*	First day: 1 mg at bedtime Maintenance: 1-20 mg in 2 doses	Sudden syncope with first dose; dizziness and vertigo; palpitation; fluid retention; headache; drowsiness; weakness; anti-cholinergic effects
DRUGS WITH CENTRAL SYMPATHOLYTIC ACTION		
Methyldopa *(Aldomet)*	500 mg to 2 grams in 2 doses	Sedation and other CNS symptoms; fever; orthostatic hypotension; bradycardia; GI disturbances, including acute colitis; acute or chronic hepatitis; cirrhosis; hepatic necrosis; Coombs' positive hemolytic anemia; lupus-like syndrome
Clonidine *(Catapres)*	0.1 to 0.6 mg in 2 doses	Severe rebound hypertension and insomnia; headache; cardiac arrhythmias after sudden withdrawal; CNS reactions similar to methyldopa, but more sedation and dry mouth; orthostatic hypotension and bradycardia similar to methyldopa; lupus-like syndrome
Guanabenz *(Wytensin)*	8 to 32 mg in 2 doses	Similar to clonidine
ARTERIOLAR DILATORS		
Hydralazine *Apresoline;* others)	40 to 300 mg in 4 doses	GI disturbances; tachycardia; aggravates angina; headache and dizziness; fluid retention; nasal congestion; rashes and other allergic reactions; lupus-like syndrome; hepatitis
Minoxidil *(Loniten)*	First day: 5 mg Maintenance: Up to 100 mg/day; usually 10 to 40 mg is adequate	Tachycardia; aggravates angina; marked fluid retention; hair growth on face and body; coarsening of facial features; possible pericardial effusions
ANGIOTENSIN-CONVERTING ENZYME INHIBITOR		
Captopril *(Capoten)*	Initial: 37.5 to 50 mg in 2 or 3 doses Maintenance: 37.5 to 450 mg (usually ≤ 150 mg) in 2 or 3 doses	Orthostatic hypotension; leucopenia; agranulocytosis; pancytopenia; proteinuria; nephrotic syndrome; membranous glomerulopathy; renal failure; urticarial rash; fever; loss of taste may lead to severe anorexia; tachycardia; acute renal failure with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney

*All antihypertensive drugs can probably cause sexual dysfunction (Medical Letter, 25:73, 1983), with the exception of angiotensin-converting enzyme inhibitors.

Propranolol *(Inderal),* **timolol** *(Blocadren),* and **nadolol** *(Corgard),* are "nonselective" beta-blockers; **metoprolol** *(Lopressor)* and **atenolol** *(Tenormin)* in low doses are "cardioselective," with a greater effect with a greater effect on the cardiac (beta$_1$) adrenoreceptors than on the beta$_2$-adrenergic receptors of the bronchi and blood vessels. However, both metoprolol and atenolol become less selective as the dose is increased, and both can cause bronchospasm in susceptible patients even at low doses. **Pindolol** *(Visken)* is a nonselective beta-blocker with intrinsic sympathomimetic activity (Medical Letter, 25:13, 1983); it can lower blood pressure without decreasing cardiac output or heart rate at rest, and may be preferable for patients who develop symptomatic bradycardia while taking other beta-adrenergic blocking drugs. **Labetalol** *(Trandate; Normodyne)* is a nonselective beta-blocker that also has alpha-adrenergic blocking properties (Medical Letter, 26:83, Sept 14, 1984). It decreases blood pressure more promptly than other beta-adrenergic blocking drugs, with hemodynamic effects similar to those produced by combining a beta-blocker with either prazosin *(Minipress)* or an arteriolar dilator such as hydralazine *(Apresoline;* others). Labetalol may cause more orthostatic hypotension and sexual dysfunction than other beta-adrenergic blocking drugs. When given with a diuretic, it was less well tolerated in one study than other beta-blockers given with a diuretic and either hydralazine or prazosin (D McAreavey et al, Br Med J, 288:106, 1984).

Prazosin *(Minipress)* blocks vascular alpha-adrenergic receptors, resulting in both arterial and venous dilatation. It causes less tachycardia than the purely arteriolar vasodilator, hydralazine, but more postural hypotension. One to three hours after the first dose of prazosin, profound orthostatic hypotension with syncope can occur; this reaction usually disappears with continued use. Hypotensive syncope can be avoided by giving a small initial dose of 1 mg at bedtime and cautioning the patient not to get up for at least three hours.

Reserpine (many brands) is an effective antihypertensive agent; other rauwolfia alkaloids and mixtures have no advantage over reserpine. A history of depression is an absolute contraindication to the use of a rauwolfia alkaloid, but severe depression can occur in patients without such a history. In doses unlikely to cause adverse reactions, reserpine alone is usually less effective than a diuretic. If reserpine is used, it should generally be at a maximum dosage of 0.25 mg daily, concurrently with a thiazide. One study showed that reserpine in doses as low as 0.05 to 0.125 mg daily combined with a diuretic was effective in many patients, and these lower doses may decrease the incidence of adverse effects (Veterans Administration Medical Centers, JAMA, 248:2471, 1982).

Guanethidine *(Ismelin)* usually decreases cardiac output and lowers systolic pressure more than diastolic. It can cause postural and exertional hypotension, which is aggravated by anything that promotes vasodilatation, including a hot environment, exercise, or alcohol ingestion. Ejaculatory failure and diarrhea are common. Because of these adverse effects, some Medical Letter consultants advise against its use. **Guanadrel** *(Hylorel)* is similar to guanethidine, with a shorter duration of action; it can also cause distressing adverse effects (Medical Letter, 25:95, 1983).

Drugs with Central Sympatholytic Action

Drugs in this category decrease sympathetic tone, but do not inhibit reflex responses as completely as those that act peripherally.

Methyldopa *(Aldomet)* frequently causes sedation and lethargy that may be transient, but can be quite disabling. It can also cause psychic depression, hemolytic anemia, and serious hepatic injury. Postural hypotension is less frequent than with guanethidine.

Clonidine *(Catapres)* has antihypertensive effects similar to those of methyldopa. It frequently causes drowsiness and dry mouth. A severe rebound in blood pressure can occur if the drug is discontinued abruptly.

Guanabenz *(Wytensin),* the newest of the centrally acting antihypertensive agents, is similar to clonidine in its effectiveness and adverse effects (Medical Letter, 25:11, 1983).

Arteriolar Dilators

Arteriolar dilators usually decrease diastolic and systolic pressures proportionately and cause little orthostatic hypotension.

Hydralazine *(Aspresoline;* and others) is often given with a beta-adrenergic blocker, such as propranolol, or a centrally acting drug, such as clonidine, to minimize the reflex increase in heart rate and cardiac output, and with a diuretic to avoid sodium and water retention. Maintenance dosage of hydralazine can be limited to 200 mg per day to decrease the possibility of a lupus-like reaction.

Minoxidil *(Loniten)* plus a diuretic and a beta-adrenergic blocking drug can usually control hypertension that cannot be controlled with other drugs (SL Linas and AS Nies, Ann Intern Med, 94:61, 1981). Minoxidil frequently causes hypertrichosis; women taking the drug should be told that they may need to shave or use other methods to remove hair for cosmetic purposes. Occasionally, patients who receive minoxidil develop a pericardial effusion, which rarely progresses to tamponade (MJ Reichgott, Clin Pharmacol Ther, 30:64, 1981).

Angiotensin-Converting Enzyme Inhibitor

Captopril *(Capoten)* is effective for both essential and renovascular hypertension (Medical Letter, 22:39, 1980). In severe refractory hypertension, it may be as effective as some three-drug regimens (RC Heel et al, Drugs, 20:409, 1980). Loss of taste, renal dysfunction, and fatal agranulocytosis have been reported, however, particularly in patients with collagen-vascular or renal disease (ED Frohlich et al, Arch Intern Med, 144:1441, 1984). The drug can cause renal failure in patients with bilateral renovascular disease or renal artery stenosis in a single kidney. Recent studies indicate that low doses of captopril (<150 mg/d) may be effective with a low incidence of adverse effects in patients with mild to moderate hypertension and without other diseases that damage the kidneys, such as diabetes (VA Cooperative Study Group, Hypertension, 5 Suppl III:III-139, 1983). Diuretics may not be required for effective therapy with captopril, but a combination of a diuretic and captopril is more effective than either drug alone.

Calcium Entry Blockers

Nifedipine *(Procardia),* **diltiazem** *(Cardizem)* and **verapamil** *(Isoptin; Calan)* are now under investigation for use in essential hypertension. All of these drugs cause vasodilatation, which decreases peripheral resistance. The cardiac response to the decrease in vascular resistance is variable; with nifedipine, a reflex increase in heart rate usually occurs, but verapamil and diltiazem produce little or no change in heart rate (Medical Letter, 25:17, 1983). Some reports indicate that these drugs, especially nifedipine, have been effective for chronic treatment of patients with mild to severe hypertension and for acute treatment of hypertensive crises (C Spivack et al, Drugs, 25:154, 1983).

MAO Inhibitor

The monoamine oxidase inhibitor **pargyline** *(Eutonyl)* has been used for treatment of hypertension. Severe adverse effects and numerous interactions with other drugs can occur, however, and Medical Letter consultants advise against prescribing it for this indication.

Combination Products

Many antihypertensive drugs are marketed in fixed-dose combinations, usually with a diuretic. Combinations of potassium-retaining diuretics with thiazides are listed in the table on page 330. Medical Letter consultants do not recommend beginning therapy with any fixed-dose combination. It is always better to adjust the dosage of each antihypertensive drug separately, especially when there are important differences in duration of action or when toxicity is dose-related. When two or more drugs are needed and the optimum maintenance doses correspond to the ratio in a combination product, there is no harm in using the combination drug, and in some patients the smaller number of tablets and doses per day may improve compliance. For further adjustment to dosage, however, it is best to use the individual drugs again.

Choice of Drugs

Thiazide-type diuretics have generally been the first drugs used for treatment of hypertension, but beta-adrenergic blocking drugs can be used just as well, particularly for patients who are white and relatively young. If a diuretic is not chosen as the initial drug and a second drug is necessary, then a diuretic should be used. If a third drug is necessary, a combination of a diuretic, a sympathetic inhibitory drug (often a beta-adrenergic blocker), and hydralazine is an effective combination.

Interactions

In addition to the frequent or severe adverse effects listed in the table on pages 330 and 331, antihypertensive drugs may interact adversely with one or more other drugs taken at the same time. These interactions are listed with recommendations for clinical management in *The Medical Letter Handbook of Drug Interactions,* 1983 and in the Drug Interactions Update published in the February 3, 1984 issue of The Medical Letter (Vol. 26, p 11).

Conclusion

Treatment with antihypertensive drugs can effectively decrease arterial pressure in almost all patients with essential hypertension. Initial therapy with a diuretic or a beta-blocker is recommended for most hypertensive patients; other drugs can be added if the response is not adequate.

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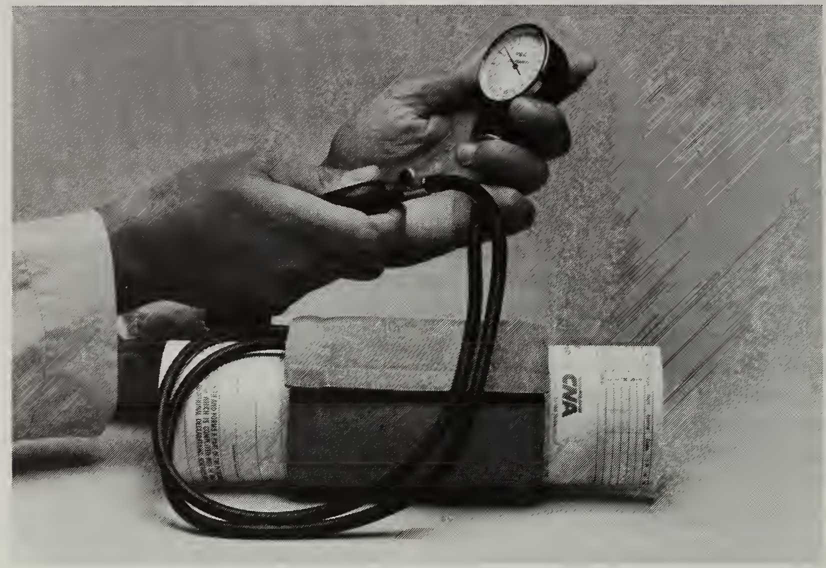

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Reflections on Medicine

The Newest Industry

ROBERT U. MASSEY, M.D.

"I remind you that we are not here to make ships. We are here to make money."

Marjorie Rosenberg in her recent essay "A Sad Heart at the Department Store" [1] took this quotation from Seymour Relman's book, *Profits Without Production,* in which it had been attributed to the chief executive officer of one of the country's great shipyards. For those of us who have watched with discomfort the growth of corporate medicine, both the essay and the book are reminders that the profit and loss statement, rather than the provision of goods and services, has become the mainspring driving both industry and the professions. Ms. Rosenberg tells a story that may someday be told of our hospitals and other medical institutions if we follow the corporate way, "—no matter how high their prices—these stores reflect their corporate owners' exploitative quest for short term profits."

Although "medicine has been the heroic exception that sustained the waning tradition of independent professionalism," Paul Starr writes in the final chapter of *The Transformation of American Medicine* "—the exception may now be brought into line with governing rule." [2]

Money has become the measure and profit the only legitimate goal in the world of the great corporate conglomerates; that medicine and the institutions of medicine should be following so rapidly and eagerly in that direction is unexpected and troubling. Toward the end of the chapter, labelled prophetically *The Coming of the Corporation,* Starr writes that "there will be corporate financing for private plans controlled by conglomerates whose interests will be determined by the rate of return on investments. That is the future toward which American medicine now seems to be headed."

It all began as things so often do with a change in the words. Patients turned into consumers of health care or, even worse, customers; physicians, nurses, biomedical scientists, and hospital directors were lumped together as providers. Almost overnight we became part of the health care industry, and no one blinked. The concept of marketing evoked reaction, even shocked disapproval from some quarters, but we were all reassured, "Everyone does it all the time. Why, doctor, even you do it when you urge your receptionist to speak courteously to your difficult patients, or, for another example, when you present a paper at a meeting, you are really marketing." Our professional behavior was assumed to be almost entirely determined by economics and motivated only by the bottom line. We were urged to compete to improve the quality of our product and keep our prices down.

"The last temptation is the greatest treason:
To do the right deed for the wrong reason." [3]

The cynics will say that nothing has changed, that no matter what was claimed, physicians, nurses, hospitals, and medical schools have always been moved by their economic self-interest; they have called it by other names—Hippocrates referred to love of the art, love of mankind—but it was all the same.

Society is unlikely to permit something as important as medical care to be left to a crowd of entrepreneurs turned corporate managers running all over the place looking for the most profitable operations to perform, diseases to treat, or communities to exploit; medicine, like education and religion, comes too close to the sacred to be left to corporate conglomerates with absentee managers; that arrangement is fine for fast food chains and discount stores, but not for hospitals, or even surgicenters. Our patients with their sounder instincts will not trust us with their health and their families' lives when we begin to act and look like just another big corporation spinning off ventures right and left. In their view our institutions have mostly been above all that; they have been special because they have been in the public service, not driven by self-interest, although no one would deny that self-interest is quite proper for business. With sound logic they understand that all of the motives of business do not apply to the professions, even though some of the rules may.

We may be losing our way. The regulators will regulate and the managers will manage, following the trend of the times, unless the physicians and nurses, keepers of the traditions, can help them all back to the high road.

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ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Editorial

Legislative Step to Contain the Spread of Cocaine Abuse

Cocaine abuse is reaching unprecedented proportions among Connecticut's under-40 population. Because of the drug's recently lowered cost and its ready availability, it is being used not only by the well-to-do, but has spread like wild fire through wide strata of white- and blue-collar workers.

The cocaine threat is still being taken too lightly by the population at large and even by segments of the medical community. The occasional user may not realize what may well be in store for him or her. Euphoria produced by the drug, and the belief that "I can stop it any time I want to," may last from months to several years before the dabbler is hooked. Various psychiatric symptoms may begin to appear early: personality changes, paranoid episodes, a tendency to deep depression and a growing inability to work or to function without resorting to more of the drug. Cocaine, it has turned out, is far more addictive than alcohol.

Because of the rapidity with which cocaine abuse is spreading, Connecticut's legislators cannot affort *not* to do something drastic. Cocaine *is* illegal and since its effects endanger not only the person who uses it but the community as well, further legislation is needed to deal with the epidemic. It would be helpful if *non-use* of cocaine were made a condition for employment in Connecticut. Beginning nine months after enactment of such a law, using or possessing cocaine, on or off the job, should be legal grounds for dismissal, as violating a condition of employment.

The U.S. government has enacted such laws in fields involving safety; and appeals courts have upheld their validity in a case where an off-duty air controller was dismissed for possession of cocaine. The courts held he had violated a condition of his employment. In safety related jobs, lawyers who specialize in civil liberty cases see no significant legal issue in this, even when urine tests for cocaine are required.

How can one define a "safety-related" job? This term should cover a wide range of occupations beyond those of pilots, firemen and policemen. Should the law not cover businesses that employ truck drivers, construction workers, train engineers and mechanics? A construction worker or a field inspector who uses cocaine on or off the job is bound, sooner or later, to become a serious hazard to others. In manufacturing plants, employers should not be bound to retain a worker who not only breaks the law, but who eventually becomes an unreliable and often dishonest employee.

If it is the law for employees covered by the FAA (which encompasses not only pilots, but a wide range of other jobs as well), equal protection should be provided for employers who are liable for the safety of their products. The law should also apply to bank employees, school bus drivers, drivers of all commercial vehicles—in fact, to all employers who are held responsible for the reliable performance of their employees—that is, to all.

Were enforcement of such a law to begin nine months after its enactment, it would enable those who dabble in cocaine to cease the practice or to seek help in doing so. Since many users still do not realize the eventual consequences of such drug use, this law would help bring into evidence the hazards to which cocaine users are subjecting themselves.

The question is bound to arise about alcohol use as it would apply to this proposed legislation. Cocaine use must be dealt with differently from alcohol abuse. First, alcohol is a legal substance; cocaine is not. Second, we have much more experience in rehabilitating alcoholics. Cocaine is not only far more addictive but, contrary to earlier and popular beliefs, it now appears to be the most addictive of the abused drugs around.

Legislative action is called for, and critical to deal with this looming threat to public health and safety.

Hans H. Neumann, M.D.

Wilton, CT.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

IN MEMORIAM

BRACELAND, FRANCIS J., Jefferson Medical College, 1930. Dr. Braceland was a psychiatrist in the Hartford County area since 1951. In 1941, he became professor of psychiatry and Dean of the School of Medicine at Loyola University in Chicago. Dr. Braceland left a year later to serve as a special assistant to the surgeon general of the U.S. Navy. He was former psychiatrist-in-chief at Hartford's Institute of Living. Dr. Braceland was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 23, 1985 at the age of 84.

HIRSHBERG, MANUEL S., Tufts Medical School, 1927. Dr. Hirshberg was a pediatrician in the Hartford County area since 1929. He was on the staffs of Hartford Hospital, St. Francis Hospital and served, as president of Mount Sinai Hospital from 1957 through 1959. Dr. Hirshberg wrote and had published many articles which appeared in the Archives of Pediatrics on Contagious Diseases during 1930-1939. He also served as physician to Bloomfield schools until his retirement several years ago. Dr. Hirshberg was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died February 18, 1985 at the age of 81.

KEDDY, RUSSELL A., McGill University School of Medicine, 1924. Dr. Keddy was a radiologist in the Fairfield County area since 1927. He was appointed full-time director of radiology in Stamford Hospital in 1929 and held that post for 32 years until his retirement in 1961. Dr. Keddy was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 23, 1985 at the age of 85.

KROSNICK, MORRIS Y., Yale University School of Medicine, 1930. Dr. Krosnick was a pediatrician in the New Haven County area since 1933. He was on the staff of Yale-New Haven Hospital and The Hospital of St. Raphael. Dr. Krosnick was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 24, 1985 at the age of 80.

LARKIN, JOHN C., Johns Hopkins Medical School, 1935. Dr. Larkin was a radiologist in the Hartford County area since 1946. He was a retired chief of radiology at New Britain General Hospital where under his direction, the hospital was one of the first in New England to use radioactive isotopes. Dr. Larkin was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 3, 1985 at the age of 78.

MOTYKA, STANLEY J., University of Kansas School of Medicine, 1938. Dr. Motyka was a radiologist in the Hartford County area since 1949. He worked with the Hartford Hospital, Institute for Living, Children's Hospital in Newington, state Veterans Hospital in Rocky Hill, Newington VA Hospital and New Britain Health Department. In 1954, the New Britain Board of Health named him director of the city's Tuberculosis Clinic. Dr. Motyka was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died January 4, 1985 at the age of 74.

PADULA, RALPH D., Cincinnati School of Medicine, 1929. Dr. Padula was an orthopedic surgeon in the Fairfield County area since 1930. He was associated with Norwalk Hospital and St. Joseph Hospital in Stamford. Dr. Padula was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died January 24, 1985 at the age of 83.

RAFFA, JOSEPH, Columbia University School of Medicine, 1934. Dr. Raffa was a general practitioner in the Hartford County area since 1935. He was a resident physician at McCook Hospital in Hartford, which closed in 1962 and a Navy physician during World War II in both Europe and the Pacific. Dr. Raffa was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 4, 1985 at the age of 76.

ROTHBLATT, REUBEN, Tufts Medical School, 1932. Dr. Rothblatt was a general practitioner in the Windham County area since 1935. Before retiring in 1977, he served on the board of Windham Community Memorial Hospital, the Windham school board, and served as health officer for the City of Willimantic. Dr. Rothblatt was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 23, 1985 at the age of 79.

YU, HENRY C., Northwestern University Medical School, 1967. Dr. Yu was a neurosurgeon in the Fairfield County area since 1973. He was on the associate staff of neurosurgery at Bridgeport Hospital and also on the courtesy staff of neurosurgery at Park City Hospital. He had been an instructor of neurosurgery with the Yale Medical School since 1976. Dr. Yu was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 11, 1985 at the age of 42.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

Council Meeting

Thursday, March 21, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Beck, Bobruff, Canzonetti, Czarsty, Dardick, Doctor, Friedberg, James, Kaess, Kamens, McDonnell, Mendillo, Orphanos, Ragusa, Robbins, Scheer, Seide, Sullivan, Jr., Sweet, Villa and Waldron.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA) and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Alisberg, Bonner, Freedman, Petrie, Reyelt, Jr., Sadowski, Schwartz, Whalen, Jr. and Zlotsky.

Reports From Physicians Serving on State and Federal Agencies

Dr. Abbot briefly summarized the activities of the Statewide Health Coordinating Council drawing particular attention to the SHCC's support of S.B. 520, An Act Concerning Applications for Certificate of Need Review by the CHHC. This proposal would require CON applicants to pay a fee which would be shared by the CHHC and the HSA.

Dr. Van Syckle commented on CAT scanner activity in Northwestern Connecticut noting that Danbury Hospital has been approved for a second scanner, while New Milford Hospital is readying its CON application.

Mr. Fiorentino summarized his report on CSMS monitoring of planning and regulatory agencies and it was received as information.

Report of the President

Inasmuch as Joseph S. Sadowski, M.D., had a long standing commitment and could not be present for the Council meeting, he directed a letter to Council Chairman Guy W. Van Syckle, M.D., for distribution to Council members. Dr. Sadowski proposed in his letter that the Council recommend to the House of Delegates that CSMS dues be increased from $175.00 to $275.00 in order to accommodate a vigorous public relations program.

It was brought out during the discussion period that the Council, at its last meeting, had authorized the expenditure of $20,000.00 to implement a preliminary public affairs program and to report back to the Council on the progress and results. It was requested that the Committee and Mr. Ray Sullivan, who joined the staff in September, 1984, have their reports in time for the House of Delegates meeting.

It was VOTED to accept Dr. Sadowski's letter for information.

Report of the Executive Director

Mr. Norbeck reported on several items:

a) *CSMS Legislative Reception:* Details of the reception following the Council meeting were reviewed.

b) *McDonald V. Haynes Medical Laboratory:* Mr. Norbeck discussed the case in which Superior Court Judge Herbert Barall recently ruled that the state's statute of limitations on medical malpractice lawsuits is unconstitutional. It is possible that CSMS will want to be involved, should the defendant appeal the case, and the Council will be apprised of future developments. The Council again reiterated its position strongly in favor of protecting the present statute.

Unified Membership

After discussion, the previous position of the Council on Unified Membership taken on December 20, 1984, was reaffirmed. The position was to "recommend to the CSMS House of Delegates that unified membership be invoked in Connecticut."

Connecticut Medical Insurance Company (CMIC) Board of Directors

It was VOTED to reaffirm approval of the nominations of the following members of the CMIC Board at the 1985 Annual Meeting of the CMIC.

Richard J. Cobb, M.D., Hartford
Edward A. Kamens, M.D., Fairfield
Gioacchino Parrella, M.D., Milford
William A. Schear, M.D., Hartford
William A. Whalen, Jr., M.D., Willimantic
Joseph P. Zeppieri, M.D., New London

NOTE: The Council had been polled by mail on February 13, 1985, and had responded in the affirmative by March 8, 1985.

Connecticut Medical Management, Inc. (CMMI)

It was VOTED to nominate the following members of the CMMI Board of Directors for election at the 1985 annual meeting of shareholders of CMMI and authorize the President of CSMS to vote the stock of CMMI owned by the Connecticut State Medical Society at the 1985 Annual Meeting of CMMI.

Sultan Ahamed, M.D., Norwich
Daniel W. Doctor, M.D., Westport
Kevin V. Dowling, M.D., Hartford
Mehdi S. Eslami, M.D., Waterbury
Jerome K. Freedman, M.D., New Haven
W. Raymond James, M.D., Essex
Mr. Timothy B. Norbeck, New Haven
James P. Orphanos, M.D., Greenwich
Joseph S. Sadowski, M.D., Hartford

It was also VOTED to place on the Council agenda, immediately prior to each House of Delegates meeting, a discussion and report on CMMI and CMIC activities and developments.

Report of Subcommittee on Preliminary Study of Nominations

With several amendments, it was VOTED to approve the report of the Subcommittee and to transmit a complete slate of nominees to the House of Delegates for election, with Council recommendation for approval.

It was VOTED that the subject of the propriety of non-CSMS members attending or acting as representatives of CSMS Sections at Society meetings be placed on the next Council agenda.

It was also VOTED to increase the membership on the following committees:

Legislation—20 to 24
Medical Aspects of Sports—20 to 24

Blue Cross/Blue Shield 2,000 Program

Guy W. Van Syckle, M.D., mentioned that a new BC/BS proposal entitled "Century 2,000 Program" had been presented to the Fairfield County Medical Association Board of Directors. The Century 2,000 Program is a Comprehensive Health Care Plan which emphasizes a Preferred Provider concept, expanded medical care benefits and a regional reimbursement methodology.

After discussion, it was VOTED to have CSMS staff immediately undertake a review and study of the various prepayment modalities now available and being proposed and to prepare an educational summary of these plans in time for a report to the House of Delegates on May 8, 1985 with a view of disseminating this information to the membership.

Life Members

It was VOTED to receive for information the following names of Life Members:

George L. Cushman, Woodbury
J. Wister Meigs, New Haven
William E. Williams, Avon

Miscellaneous

Auxiliary to CSMS

Marilyn Eslami reported to the Council that she had been appointed to the Connecticut Alcohol and Drug Abuse Council (CADAC).

Mrs. Eslami further reported on the wide acceptance of the seat belt logos and the auxiliary's involvement in the "Ronald McDonald House" in New Haven.

After her presentation, the Council VOTED its endorsement of the National Federation of Parents for Drug-Free Youth, with the understanding that such endorsement would not require CSMS to receive or disburse or in any way be responsible for federal grant funds.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 21, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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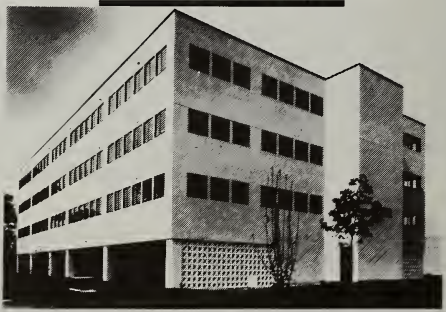
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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Farmington Valley, CT. Full time emergency physician needed immediately for walk-in treatment center. Opportunity for full partnership. Write CSMS, c/o EM/JR.

Full and part-time emergency room opportunities available for qualified primary care physicians in Central CT and Windham county. For information and application contact the recruitment department at 1-800-645-4848.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

EMERGENCY MEDICINE/FAMILY PRACTICE

Cromwell, Connecticut seeks high quality physician for Ambulatory Care, Freestanding Walk-in Medical Center. Position available for full and part-time. Emergency Medicine and or Family Practice physician desired with strong communication and marketing management skills. Reply with C.V. and cover letter stating availability and salary requirements to: Gail Brown, Medical Center Consultants, 2279 Grand Island Blvd., Grand Island, New York, 14072.

FAMILY PRACTICE

Board certified physician seeks associate to join well-established, expanding family practice, partnership available. Located in medium-sized central Connecticut community, ½ hour from Hartford. Modern 250 bed community hospital, coverage available, no obstetrics. Contact Anne Sondek, Four-CN Vermont Street, Buffalo, New York 14213, (716) 884-3700.

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Family physician to join board certified residency trained family practitioner in a growing, two office practice in Guilford or Essex on the shoreline. Beautiful area; enjoyable life style; excellent schools. Great opportunity for professional and personal satisfaction. Will consider part-time. Reply to, Alan Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

FAMILY PRACTICE/INTERNAL MEDICINE

Family Practitioner or Internist, Newington, CT, to practice medicine in a small State psychiatric hospital, ten minutes from Hartford. A 130 bed facility, accredited and certified, provides acute/intermediate psychiatric treatment. Position available April 1, 1985. Salary is commensurate with experience and training. Excellent benefit package. Connecticut license required. Send resume to Arnold W. Johnson, M.D., Chief of Professional Services, Cedarcrest Regional Hospital, 525 Russell Rd., Newington, CT 06111. AA/EEO.

Family practitioner or internist needed immediately as third MD in a Southeastern Connecticut practice. Salary on first year and partnership starting the second year. Send CV to 26 Lafayette St., Norwich, CT 06360.

INSTITUTIONAL MEDICINE

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JCAH-Accredited 350-bed State Hospital seeks the services of a board eligible physician with experience or interest in Respiratory Therapy and a willingness to participate in limited administrative functions. Work week of five days, 35 hours with liberal State fringe benefits. Send C.V. to R.J. Cavalieri, M.D., Chief of Medicine, Veterans Home and Hospital, 287 West St., Rocky Hill, CT 06067.

Walk-In Medical Services is seeking full and part time physicians to work in a convenience medical facility in Orange, CT. FAM. PRAC/IM preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Growing, federally qualified HMO in Southwestern CT seeks BC/BE Internist. Emphasis on personalized, cost-effective, medicine. Competitive salary, comprehensive fringe benefits, teaching appointments to university-affiliated hospitals. Submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Connecticut Health Plan, 4000 Park Ave., Bridgeport, CT 06604. Telephone (203) 371-1534.

PRIMARY CARE

Physicians—Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

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PRACTICE FOR SALE

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

Internal Medicine/Cardiology practice for sale; Northern Connecticut; close to Hartford and Springfield, MA. Flexible financial arrangements. Write to SALE/JR, c/o CSMS.

PSYCHIATRY

Child Psychiatrist needed for full to part-time, in greater Hartford area, to join a well established office and hospital practice. Reply to CSMS, PSY/MN.

RADIOLOGY

Radiologist wanted part-time for general diagnostic radiology in private office practice in Waterbury area. All replies confidential. Write CSMS c/o RAD/AA.

PHYSICIAN WISHING TO LOCATE IN CONNECTICUT

ALLERGY/IMMUNOLOGY

Availability negotiable. Presently in practice. Age 31. Nat'l bds. AB cert. (PED); AB elig. (ALL & IMM). MD. University of Vermont; Int. and Res., Columbia Presbyterian Medical Center; Fellowship, University of California, San Francisco, CA. Prefers group or associate type practice (Allergy/Immunology) in a medium to large-sized community. Write, David J. Valacer, M.D., 42 Wachusett Ave., Shrewsbury, MA 01545.

DERMATOLOGY

Feb. '85. Licensed in Connecticut. Presently in practice. Age 35. FLEX. AB cert. MD, University of Oklahoma; Int., Hospital of St. Raphael (Med/Surg); and Res., St. Francis Hospital, Hartford (Path), Henry Ford Hospital, Detroit (Derm). Interested in clinical dermatology and will consider a part-time position. Would also consider solo, group or associate type practice in a medium to large-sized community. Write, Lawrence J. Fortier, M.D., 1350 W. Bethune Ave., Apt. 509, Detroit, MI 48202.

FAMILY PRACTICE

July '85. Age 28. Nat'l bds. AB elig. MD, Upstate Medical Center, SUNY, Syracuse, NY; Int. and Res., University of Maryland Hospital. Prefers group or HMO type practice in a medium to large-sized community. Write, CSMS, c/o SL/FP.

Aug. '85. Age 34. Nat'l bds. AB elig. MD, University of Colorado, Denver, CO; Int. and Res., Kaiser Permanente, Fontana, CA. Prefers group type practice in a medium-sized community. Write, Barry R. Hansen, M.D., 919 Emerson Pl., Clarement, CA 91711.

July '85. Age 38. Licensed in Connecticut. AB elig. MD, T.N. Medical College, Bombay, India; Int. and Res., Medical Center of Central Georgia, Macon, GA. Interested in group, associate, institutional or HMO in a community of 20,000-30,000 within 30-40 miles of big metropolis for CME and referral. Write, Kamrudin K. Mithani, M.D., 3540D Lake Terrace Pl., Macon, GA 31204.

GENERAL PRACTICE

March '85. Age 38. Licensed in Connecticut. MD, S.M.S. Medical College, Jaipur, India; Int., Doctor's Hospital, Toronto, Canada; Res., St. Joseph's Hospital, Toronto; University of Toronto (Psychiatry). Prefers solo, group, associate or industrial type practice. Write, Nalini Menon Pathiyal, M.D., Apt. A-2, 9 Concord St., West Hartford, CT 06119.

INTERNAL MEDICINE

GASTROENTEROLOGY. July '85. Age 30. Nat'l bds. AB Cert. MD, NY University; Int. and Res., Downstate Medical Center, King County Hospital; Fellowship, NY Medical College. Desires solo, group or associate type practice. Write, CSMS, c/o MCB/IM.

Immediately available. Age 36. Licensed in Connecticut. Nat'l bds. AB Cert. MD, Universidad Autonoma de Guadalajara; Int. and Res., Elmhurst City Hospital. Interested in private practice in a small-sized community but will consider group or associate also. Write, Gary Bykoff, M.D., 32-42 89th St., Jackson Heights, NY 11369.

Aug. '85. Age 28. AB elig. MD, Mysore Medical College; Int. and Res., Grant Hospital of Chicago. Prefers group, institutional or industrial type practice in a large-sized community. Write, Benu Chatterjee, M.D., #459, 535 W. Briar, Chicago, IL 60657.

July '85. Age 29. FLEX. AB elig. MD, Indiana University School of Medicine; Int. and Res., University of Cincinnati. Prefers small to medium-sized community group or associate type practice in a small to medium-sized community. Write, Douglas J. Trigg, M.D., 515 Howell Ave., Cincinnati, OH 45220.

Sept. '85. Age 28. Nat'l bds. AB elig. MD, University of Washington; Int. and Res., Kaiser Foundation Hospital, San Francisco, CA. Prefers group, associate or institutional type practice in a medium to large-sized community (western Connecticut). Write, Susan K. Elgee, M.D., 85 Kent Court, #12, Daly City, CA 94015.

July '85. Presently in practice. Age 29. Nat'l bds. AB cert. MD, Downstate Medical School; Int. and Res., Brookdale Hospital, Brooklyn, NY. Prefers group, associate, institutional and industrial type practice within commuting distance of Stamford. Write, Catherine Cohen-Troy, M.D., 435 E. 79th St., Apt. 12-B, New York, NY 10021.

PULMONARY. July '85. Age 31. FLEX. AB cert. (IM). MD, Mahatma Gandi Memorial Medical College, Indore, India; Int. and Res., St. Clare's Hospital, New York, NY and Jamaica Hospital, New York, NY; Fellowship, St. Vincent's Hospital, Worcester, MA. Prefers solo, group or associate type practice in a medium-sized community. Write, Surendra K. Nevatia, M.D., 21 Heywood St., #2E, Worcester, MA 01604.

GASTROENTEROLOGY. July '85. Age 33. FLEX. AB cert. M.B.B.S., Baroda Medical College, M.S. University, Baroda, India; Int., Res. and Fellowship, Bronx-Lebanon Hospital, Bronx, NY. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Pravin N. Patel, M.D., 15 St. Andrew's Pl., #2J, Yonkers, NY 10705.

GASTROENTEROLOGY. July '85. Licensed in Connecticut. Age 33. FLEX. AB cert. (IM); AB elig. (GI). MD, Peruvian University Cayetano Haredia, Lima, Peru; Int. and Res., St. Vincent's Medical Center, Bridgeport, CT; Fellowship, St. Vincent's Medical Center (Yale affiliated GI program). Wishes group or associate type practice. Write, Hector R. Pun, M.D., 55 Fifth Ave., Stratford, CT 06497.

NEUROLOGY

Immediately available. Presently in practice. Age 36. FLEX. AB cert. (IM); AB elig. (NEUR). MD, University Bologna; Int. and Res., Nassau Hospital, Mineola, NY; Fellowship, University of Miami, Miami, FL. Prefers solo, group or associate type practice. Write, CSMS, JCMC/NEUR.

RADIOLOGY

DIAGNOSTIC. March '85. Age 33. Presently in practice. Nat'l bds. AB elig. MD, SUNY Buffalo School of Medicine; Int., University of Wisconsin Hospitals, Madison, WI; Res., Baystate Medical Center, Springfield, MA. Is flexible in practice consideration and wishes to practice in a small to medium-sized community. Write, CSMS, c/o LI/RAD.

SURGERY

GENERAL/VASCULAR. Immediately available. Age 39. FLEX. AB elig. M.B., Ain Shams University, Cairo, Egypt; Int. and Res., Mount Vernon Hospital, Mount Vernon, NY; Fellowship, Texas Heart Institute, Houston, TX and Baylor College of Medicine, Houston. Prefers group or associate type practice in a medium-sized community. Write, Wagih R. Mando, M.D., 7107 Hillcroft ffl404, Houston, TX 77081.

March '85. Presently in practice. Age 32. Nat'l bds. AB elig. MD, University of California, San Francisco School of Medicine; Int. and Res., University of California, San Francisco-Central San Joaquin Medical Education Program. Prefers multi-specialty group in a medium to large-sized community. Write, Eric E. Jones, M.D., P.O. Box 23656, Baltimore, MD 21207.

Heart Transplantation: 1985 Perspective

JAMES E. DOUGHERTY, M.D., MICHAEL A. ROSSI, M.D., ALFREDO F. NINO, M.D.,
HENRY B.C. LOW, M.D. AND ROBERT T. SCHWEIZER, M.D.

ABSTRACT—Over 1,100 cardiac transplant procedures were performed in the world between January, 1968 and December, 1984. During this period cardiac transplantation has become an increasingly successful therapy for patients with end-stage cardiac disease. Coronary artery disease and cardiomyopathy together represent greater than 90% of the diseases in patients undergoing cardiac transplantation. The present success of orthotopic cardiac transplantation is the direct result of the efforts of a few pioneers who developed the surgical techniques, criteria for recipient selection and guidelines for post-operative management and long-term follow up. Approximately 83% of cardiac transplant recipients are reported to be alive after one year and greater than 50% after five years. This improved survival rate has been attributed in large part to recent advances in right ventricular endomyocardial biopsy and cyclosporine therapy and is the basis of growing enthusiasm and interest in heart transplantation.

Experimental heart transplantation was first reported by Carrel and Guthrie in 1905.[1] The operation lasted one hour and fifteen minutes and the experiment was terminated several hours later when thrombosis occurred within the heart. The next important experimental advancements were improvements in surgical technique and short-term heart preservation developed by Lower and Shumway in 1961.[2]

The first human to human heart transplant procedure was performed by Barnard and associates in December, 1967.[3] The technical aspects had been well studied in animals which permitted an uncomplicated operation. The transplanted heart functioned well. However, the patient succumbed to a combination of rejection and infection as did many transplant recipients that followed. During the next two years over 150 operations were performed by 40 teams in 17 countries. Enthusiasm soon waned, however, after the continued problems of rejection and infection resulted in poor survival. During the early 1970's heart transplantation continued at only four centers: Stanford University, Medical College of Virginia, La Pitie' Hospital in Paris, and Capetown, South Africa. The clinical experience and results of research from these groups formed the basis for a renewal of interest in clinical heart transplantation by other centers.

Owing to improvements in survival rate and the quality of life of the recipients, a resurgence of interest in heart transplantation is ongoing in this country and worldwide. This is indicated by the increased number of heart transplant procedures reported to the International Heart Transplant Registry (Table 1). The transplant registry contains data from transplant centers in North America, Great Britain, France, Germany and Scandanavia.[4]

Table 1
TRANSPLANTS PERFORMED

Before 1978	181
1978	53
1979	39
1980	70
1981	81
1982	151
1983	229
1984	390

JAMES E. DOUGHERTY, M.D., Assistant, Department of Medicine, Division of Cardiology, Hartford Hospital; Clinical Instructor, Department of Medicine, University of Connecticut School of Medicine. MICHAEL A. ROSSI, M.D., Senior, Department of Medicine, Division of Cardiology, Hartford Hospital; Clinical Instructor, Department of Medicine, University of Connecticut School of Medicine. ALFREDO F. NINO, M.D., Senior, Department of Medicine, Division of Cardiology, Hartford Hospital; Clinical Instructor, Department of Medicine, University of Connecticut School of Medicine. HENRY B.C. LOW, M.D., Senior, Department of Surgery, Hartford Hospital; Assistant Professor of Surgery, University of Connecticut School of Medicine. ROBERT T. SCHWEIZER, M.D., Senior, Department of Surgery; Chief, Transplantation Service, Hartford Hospital, Hartford, CT; Associate Professor of Surgery, University of Connecticut School of Medicine, Farmington, CT.

Reprint requests to: 85 Jefferson St., Hartford, CT 06106 (Dr. Dougherty).

Indications

Cardiac transplantation can now be considered suitable treatment for selected patients with end-stage cardiomyopathy.[5, 6] Coronary artery disease and cardiomyopathy together represent greater than 90% of transplant patients. Valvular heart disease, congenital heart disease and cardiac tumor have also been described as less common diseases resulting in cardiac transplantation.[6] Recipients are usually under 55 years of age and although an upper age limit has been set by many centers we permit flexibility and individual assessment of the older patient. In general, suitability is based upon the likelihood of survival and realistic post-operative rehabilitation.

Criteria for exclusion from transplantation are the following: 1) active infection, 2) malignancy, 3) elevated and fixed pulmonary vascular resistance exceeding four to six Wood units, 4) active peptic ulcer disease, 5) severe obstructive lung disease, 6) severe psychiatric disease, 7) morbid obesity, and 8) drug addiction. Patients with Type I diabetes mellitus are excluded by some centers because of the fear of difficult management secondary to corticosteroid administration. Our experience with diabetic kidney transplant patients is such that glucose control is no longer an absolute contraindication. Diabetics being considered for heart transplantation, however, should not have advanced microangiopathic or peripheral vascular disease.

The potential transplant recipient must have New York Heart Association (NYHA) Class IV or progressive Class III cardiac disability refractory to aggressive conventional medical or surgical therapy. The stringent criteria for transplantation are reflected in the Stanford University experience.[7] They reported that only 10% of the patients referred for cardiac transplantation were selected as potential candidates, and of these, only one-half ultimately underwent cardiac transplantation. Although other centers report slightly differing statistics, all strongly emphasize a high degree of patient selectivity regarding heart transplantation candidacy.

Donor Selection and Procurement

In 1968, when Shumway and associates embarked upon clinical heart transplantation, there was no consensus regarding the definition of brain death.[8] Legal, medical and ethical guidelines are currently based upon the criteria established by the Harvard ad hoc committee on irreversible coma of 1968.[9] These guidelines permit the procurement of organs without undue delay and provide legal protection for the potential donor. In 1978, Connecticut passed the first brain death legislation in New England allowing for the determination of death following the establishment of total and irreversible loss of brain function.

The majority of potential organ donors have sustained major cerebral damage secondary to blunt trauma, gunshot injury, anoxic brain damage, or intracranial vascular catastrophe. The upper age limit for a suitable heart donor is approximately 30 years for males and 35 years for females so as to reduce the possibility of occult atherosclerotic heart disease. Cardiac function must be normal. Cardiopulmonary resuscitation, severe and prolonged hypotension and the need for high dose vasopressor administration are all relative contraindications.[10] Donor management can often be complex because of rapid fluid shifts, the need for respiratory support and the physiologic changes accompanying brain death. A patient must therefore be maintained in an optimal condition for organ donation and treated in an intensive care unit setting with special attention to fluid and electrolyte balance.

Cardioplegic arrest followed by ice cold electrolyte solution storage permits myocardial preservation of the donor heart for up to four hours. Utilizing this technique, transplant centers can transport a donor heart from 500-800 miles with optimal coordination and transportation.[11] Current research is presently directed at measures to expand these constraining time limits of heart donor availability and procurement.

Surgical Technique

The operative techniques in current use are largely unchanged from those developed in the laboratory by Lower and Shumway.[2] Removal of both the donor and diseased recipient heart are similar although the latter is done with full cardiopulmonary bypass.[12] The aorta and pulmonary artery are transected, but the posterior portions of the atria with the vena cava and pulmonary veins are left intact within the recipient. This technique avoids the need for the anastomosis of those individual vessels (Figures 1-2). The donor heart is implanted, beginning with the atrial anastomoses and followed by the great vessel anastomoses. Standard open heart cannulation and cardiopulmonary bypass is employed, medastinal drainage tubes are placed and temporary pacing wires are implanted. Hemostasis is given particular attention in view of the several long suture lines. A special effort is also made to remove air from the cardiac chambers prior to removal of the aortic cross clamp.

Post-Transplant Care and Immunosuppression

The immediate post-operative care of the patient who has undergone orthotopic heart transplantation is similar to that of any patient undergoing cardiopulmonary bypass. The exceptions relate to the denervated cardiac electrical system and immunosuppressive therapy with its attendant need for regulation and monitoring.

Infusions of dopamine or isoproterenol are used after surgery to increase the ionotropic and chronotropic abilities of the transplanted heart. The transplant patient is unique in that each has two sinus nodes—the recipient sinus node showing electrical, but no functional activity, and the donor sinus node driving both the atria and ventricles. The recipient sinus node remains viable via bronchial collateral vessels and is functionally responsive to autonomic stimulation.[13, 14] The transplanted donor heart remains totally and permanently denervated. Hence, two sets of atrial P waves can be recorded on the standard electrocardiogram (Figure 3). This unique situation is important in the pharmacologic management of the heart transplant patient.

Before cardiac transplantation is performed, both ABO donor–recipient compatibility and negative donor-recipient lymphocyte serologic cytotoxicity must be established. The paucity of heart donors and time restraints preclude the use of HLA tissue matching in heart transplantation.

Transplant patients require life-long immunosuppressive therapy to minimize and control rejection episodes although doses are gradually tapered to an acceptably low maintenance level. Immunosuppression must also be kept at a minimum in order to reduce the incidence of infection. Consequently, constant surveillance is necessary to monitor for rejection and infection. Balanced immunosuppression is currently achieved through a combination of medications including corticosteroids, cyclosporine, azathioprine, and occasionally antithymocyte globulin.[15] Newer immunosuppressive agents will soon be employed.

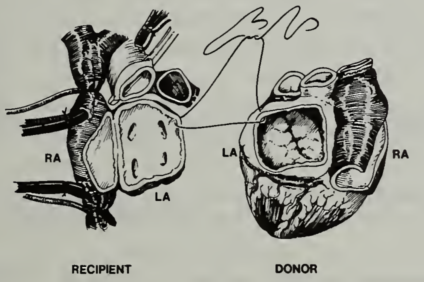

Figure 1
The recipient is cannulated similar to a routine open heart procedure except for more posterior placement of the venous cannula. The transplantation procedure begins by anastomosing the left atrium of the donor heart to that of the recipient beginning at the level of the left superior pulmonary vein. The superior vena cava has been closed with staples.

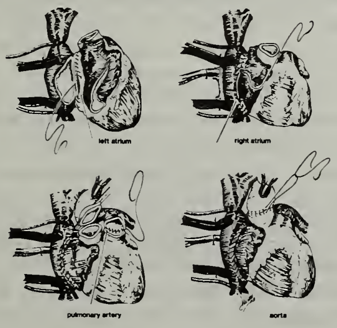

Figure 2
Left upper: The left atrial anastomosis is being completed. *Right upper:* The right atrial anastomosis is near completion. Note that a left ventricular sump catheter has been inserted through the right superior vein before the right atrial anastomosis is started. *Left lower:* The main pulmonary artery is being anastomosed. Some transplant surgeons prefer completing the aortic anastomosis first to reduce ischemic time. *Right lower:* The final step is the anastomosis of the donor aorta and the recipient aorta. Between each anastomosis cold blood cardioplegic solution is infused to help with myocardial preservation.

Cyclosporine is perhaps the most important agent currently administered for immunosuppression. Since its introduction for clinical transplantation in 1978, cyclosporine has been extensively used in all areas of organ transplantation.[16,17] Cyclosporine is a naturally occurring peptide which attacks certain T-cells involved with the rejection process. Unlike azathioprine, cyclosporine does not often depress bone marrow function. Lower doses of concurrent corticosteroids are permitted with cyclosporine immunosuppression, thereby helping to reduce the incidence and severity of the infectious complications that were common with high dose steroids and azathioprine. The combination of reduced rejection severity and less severe infectious complications has decreased the post-operative transplant hospitalization period and the overall cost of organ transplantation.[17, 18] One significant disadvantage of cyclosporine is potential nephrotoxicity when used in high doses.[19, 20] Consequently, cyclosporine blood levels are required regularly for monitoring the drug dosage in order to maximize immunosuppression while limiting concomitant nephrotoxicity.

The early and accurate diagnosis of rejection episodes is essential in the management of organ transplant recipients. In the heart transplant patient, right ventricular endomyocardial biopsy is now the most sensitive and specific means for diagnosing acute rejection. The current technique was developed by Caves, et al in 1973.[21] Prior to the use of cyclosporine, electrocardiographic voltage

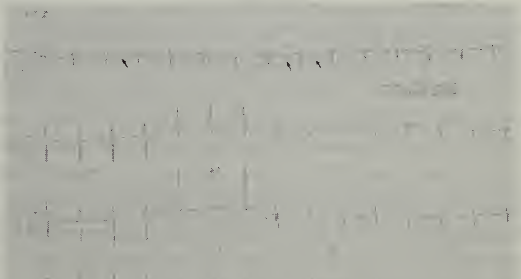

Figure 3
Orthotopic cardiac transplant 12 lead electrocardiogram demonstrating duel atrial foci (2 P waves) in addition to non-specific ST-T wave changes. Note the arrows which direct attention to double atrial activity.

measurements could be used to monitor for rejection. Since cyclosporine largely prevents those voltage changes, endomyocardial biopsy is currently the only reliable method for diagnosing early rejection and assessing the results of therapy.[22]

The methodology and clinical safety of right heart biopsy has been recently reviewed in *Connecticut Medicine.*[23] Biopsies are usually obtained one week after transplantation and are repeated once a week during the first two months. Biopsies may be acquired more frequently if necessary and are performed within 72 hours after a rejection episode has been treated. A dedicated team of cardiac pathologists specially trained in the interpretation of transplant heart biopsies is essential to the management of transplant patients.

Results

Survival statistics following cardiac transplantation have improved yearly. The greatest achievement of heart transplantation, however, has been the improvement in quality of life of the recipients and the ability to return to a functional and productive life style. This is demonstrated by the Stanford series of 106 one year survivors, 97% (103 patients) of whom were NYHA class I cardiac status.[24] These patients were all NYHA class IV prior to heart transplantation and had an expected survival of not longer than 6-9 months.

Since the advent of cyclosporine, actuarial survival statistics have improved dramatically. At present, the one-year survival rate following cardiac transplantation has risen to 83% and the expected survival rate at five years to more than 50%.[25] The increased survival figures with the use of cyclosporine occur both at three months and one year. These improvements are due to better immunosuppression and improved monitoring with right ventricular endomyocardial biopsy. Infection and acute rejection remain the two most common causes of death, followed by chronic rejection and graft atherosclerosis in long-term survivors.

Discussion

Considerable progress has occurred over the past 17 years since Christian Barnard performed the world's first heart transplant in Capetown, South Africa. In the United States, the Stanford University Medical Center team headed by Dr. Norman Shumway continued the clinical research necessary to bring orthotopic heart transplantation from the realm of the experimental to that of the therapeutic. The process, however, has not been an easy one. Only six years ago, an editorial in the *New England Journal of Medicine* discussed the decision by the Massachusetts General Hospital (MGH) not to begin heart transplantation.[26] It was concluded that cardiac transplantation, under certain conditions, could be considered for a select group of patients with end-stage cardiac failure, but that its use should be limited. Questions relative to its cost-effectiveness were also raised. The decision by the MGH prevented many institutions from considering a heart transplant program.

Despite the MGH decision, laboratory research in heart transplantation with a goal towards clinical application continued at several advanced organ transplant centers across the country, including Hartford Hospital. The gradual, but steady improvement in survival statistics was the primary basis for this continued interest. The striking results specifically relating to cyclosporine, however, accelerated enthusiasm for transplantation. In November, 1984, a follow-up *New England Journal of Medicine* editorial by the MGH recognized these changes.[27] Based upon improved survival and rehabilitation results, it stated "it is clear that cardiac transplantation has not been generally accepted as a therapeutic intervention of proved value."

Multiple clinical trials have now corroborated cyclosporine to be both powerful and immunospecific, allowing for reduced rejection and equally important, better clinical tolerance of rejection episodes. This in turn has resulted in shorter hospitalizations and fewer complications following transplantation with a concurrent reduction in cost. With these results, cardiac transplantation has become established as an important therapy for selected patients with end-stage cardiac disease. It is anticipated that in 1985, cardiac transplantation will become even better established in Connecticut and worldwide as a major therapeutic advance for this patient group.

Acknowledgement: The authors are grateful to David W. Low, M.D., for the illustrations of cardiac transplantation technique.

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Primary Mesenteric Venous Thrombosis with Recurrence

S.J. CASERTA, M.D., WILLIAM H. CURLEY, M.D. AND M. DAVID DEREN, M.D.

ABSTRACT–Survival of a patient, ill with recurrent primary mesenteric venous thrombosis, followed operative resection to include normal bowel and mesentery. Early adequate dose of anticoagulant started immediately postoperative is vitally important. Feasibility of long term anticoagulant therapy in the presence of a likely hypercoagulable state should be seriously considered.

Primary mesenteric venous thrombosis occurs most infrequently. Hansen and Christofferson[1] report an incidence of .01% of this disease proven at surgery or autopsy, after evaluating the records of all patients seen in two hospitals in Copenhagen between 1963 and 1973. At Massachusetts General Hospital between 1960 and 1965, with a similar survey,[2] the incidence was .06%. The diagnosis preoperatively remains elusive. Postoperatively, the threat of recurrence of the disease is to be taken seriously by the attending physician. Jona[3] reports a rate of 29% recurrence.

Case Report

This was a 53-year-old building contractor admitted to St. Vincent's Medical Center on 3/29/57. He was well until two weeks prior to admission when he began to experience an ache in the epigastrium and towards the left side of the abdomen. It would occur usually in the early afternoon and at irregular intervals throughout the rest of the day. The ache was described as a "full feeling" or cramplike "as though something was not getting through." At times the pain would improve during the two weeks, but it never actually left him. It was not relieved with antacids. He denied having symptoms of vomiting, diarrhea or tarry, bloody stools. The pain was associated with moderate anorexia and constipation. A gastrointestinal series four days prior to admission was reported as normal.

The past history disclosed an episode of acute thrombophlebitis in 1954 of the right lower extremity provoking marked swelling of the entire extremity. He was left with a residual of mild to moderate nonpitting edema to the level of the mid thigh. Starting at the age of 40 he suffered from large hemorrhoids.

His father also suffered from large hemorrhoids, and a severe acute thrombophlebitis at the age of 46 affecting the entire right lower extremity.

On admission the temperature rectally was 99.4 degrees, the pulse was 100 and the respirations were 20. The blood pressure was 130/80 mm Hg. The patient did not appear to be acutely ill. The abdomen was soft and slightly distended. Moderate tenderness was elicited on deep pressure in the epigastrium and left upper quadrant. Bowel sounds were slightly hyperactive. A rectal examination was normal. The most likely diagnosis appeared to be acute pancreatitis. The surgical consultant* included acute mesenteric venous thrombosis and dissecting aneurysm in the differential diagnosis.

S.J. CASERTA, M.D., Former Consultant, Department of Internal Medicine, Division of Pulmonary Disease. WILLIAM H. CURLEY, M.D., Consultant, General Surgery; Former Chief of Surgery, Department of Surgery. M. DAVID DEREN, M.D., Former Consultant, Department of Internal Medicine; all of St. Vincent's Medical Center, Bridgeport, CT.

*William H. Curley, M.D., Consultant in general surgery, St. Vincent's Medical Center

The white cell count was 12,600 with 66 percent neutrophils, 22 percent lymphocytes, nine percent band forms and three percent eosinophils. The hematocrit was 43 percent and the hemoglobin 13.5 gms. The serum amylase was 58 units per DL (normal 50 to 200 units per DL). The remainder of the laboratory results including bilirubin, alkaline phosphatase, glucose, urea nitrogen, serum proteins, electrolytes and urinalysis were all normal. Flat and upright films of the abdomen revealed gas in the ascending and transverse colon. No fluid level was present. X rays of the chest and an electrocardiogram were normal.

During the night the pain became much more severe and persistent with no significant relief from demerol. In the morning the abdomen was noted to be appreciably distended. Bowel sounds were absent. Flat and upright films of the abdomen showed dilated small intestinal loops in the left upper quadrant with fluid levels that appeared as a high small intestinal obstruction. It became obvious that the patient had an acute abdomen, and an immediate laparotomy was indicated.

At surgery a segment of jejunum, approximately one foot in length and one foot from the ligament of Treitz, appeared boggy in consistency, reddish purple in color. Its mesentary showed thrombosis of its vessels. In view of the questionable viability of this segment of bowel, it was resected and an end to end anastomosis (jejuno-jejunostomy) was performed. The gall bladder and pancreas appeared normal. A large amount of cloudy peritoneal serous fluid was present.

Pathologically, the resected segment of small intestine measured 34 cm. in length with attached piece of mesenteric fat. The serosal surface of the intestine and mesentery was reddened and roughened. On each end of the specimen was a segment of normal appearing serosa. On section the wall of the intestine was quite thickened and reddish. Numerous sections through the mesenteric fat disclosed the blood vessels to be occupied by firm adherent, reddish blood clots. Microscopically, sections showed the intestine to be the site of extensive hemorrhagic necrosis involving the entire wall. Sections from the mesentery revealed the thrombi to involve the veins only, the arteries being free of histopathologic changes. Pathological diagnosis: Mesenteric venous thrombosis and hemorrhagic necrosis of jejunum.

For the first four postoperative days, the temperature was either normal or slightly elevated. He experienced slight nausea. There was a small amount of drainage from the Levine tube. The abdomen remained soft. During this period of time his postoperative course was considered to be entirely satisfactory.

Depoheparin was given as follows: 200 mgm at 11 p.m. on the day of surgery, 1 gm on the first postoperative day and 200 mgm on the second day. The Lee-White clotting times from the first and through the fifth postoperative days were: 8 minutes, 4 minutes 30 seconds, 9 minutes, 6 minutes 50 seconds, and 6 minutes 40 seconds. The dicumarol was started on the first postoperative day. It was given through the Levine tube, which was clamped for 1½ hours each time. The daily dose from the first to the fifth postoperative days was: 300 mgm, 200 mgm, 100 mgm, 150 mgm, and 100 mgm. The corresponding prothrombin times were: control 14 seconds, patient 25 seconds; control 12 seconds, patient 19 seconds; control 12 seconds, patient 17 seconds; and finally, control 13 seconds, patient 15 seconds.

On the fifth postoperative day at 6 a.m., the patient was experiencing severe pain in the right lower quadrant. It had started at 10 p.m. the previous evening, and the pain had become progressive in nature. The temperature at 6 a.m. was 100°, pulse 112 and the blood pressure 140/80. Examination of the abdomen revealed the presence of pronounced distention and exquisite tenderness in the right lower quadrant as well as rebound tenderness. Flat and upright films of the abdomen showed scattered small bowel distended loops with air fluid levels, more pronounced in the left upper quadrant. The patient was immediately taken to surgery. At operation gangrene of the jejunum was found, beginning in the anastomosis and extending along the bowel for approximately three feet. There was thrombosis of the mesenteric vessels near the bowel. There was present a large amount of serosanguinous fluid in the peritoneal cavity. The anastomosis appeared patent and intact. The jejunum was divided approximately 5 inches proximal to the anastomosis. The anastomosis between the jejunum and ileum was then performed in an end to end fashion.

On the second postoperative day the patient vomited 300 cc. of dark green fluid. A Levine tube was inserted, and it immediately drained 400 cc. of the same type of fluid. In all, for 24 hours, the patient drained 3,900 cc. of fluid through the Levine tube. He was given 4,000 cc. of fluid intravenously. His temperature was 101°. The following day serum electrolytes were: sodium 145 mmol, chlorides 94 mmol, potassium 4.7 mmol and carbon dioxide capacity 52 volumes percent. Thereafter his temperature remained essentially normal throughout the remainder of his hospital stay despite the complication of a large abdominal wound abscess.

Immediately following surgery the patient was given 300 mgm of depoheparin. It was repeated in the same dose on the evening of the same day. One last dose of 200 mgm was administered on the first postoperative day. At 11 p.m. on the day of surgery the Lee White clotting time was ten minutes. The following morning at 9:30 a.m. it was 48 minutes and at 3 p.m. the same day, 24 minutes. For the next three days it was 15 minutes 35 seconds, 17 minutes 30 seconds, and finally, 9 minutes and 45 seconds.

Dicumarol was started on the first postoperative day down the Levine tube which was clamped for 1½ hours each time. The daily dose from the first through the fourth postoperative days was: 300 mgm, 150 mgm, 150 mgm, 150 mgm and 250 mgm. The prothrombin times on these successive days were: control 13 seconds, patient 26 seconds; control 14 seconds, patient 30 seconds, control 14 seconds, patient 25 seconds; and control 13 seconds and patient 19 seconds. The day following the dicumarol dose of 250 mgm, the prothrombin control was 14 seconds, and the patient, 90 seconds! No dicumarol was given that day. Hykinone 75 mgm was ordered. Fortunately, the patient showed no signs of bleeding. The next morning the hematocrit was found to be 47 percent and the hemoglobin 12 gms. A urinalysis was normal. The control was 14 seconds and the patient's prothrombin time, 35 seconds. On this day he was given 50 mgm of dicumarol.

For the next five postoperative days the patient's prothrombin time was kept at two to two-and-a-half times the control with doses of 100 mgm and 150 mgm of dicumarol on alternate days. Thereafter, to the time of discharge, the dicumarol dose varied between 75 mgm to 100 mgm. Subsequently for the next 15 years the dicumarol dose stabilized at 50 mgm to 75 mgm daily. In the next 12 years the anticoagulant was changed to warfarin sodium at a daily dose of 5 mgm, occasionally increased to 7.5 mgm. The prothrombin time became fairly predictable when taken once or twice monthly. Except for interruptions of surgery three years ago for a prostatectomy at Lahey Clinic, and one and a half years ago for a cholecystectomy at St. Vincent's Medical Center, the patient has been on continuous anticoagulant therapy for the last 27 years. During this period of time, the patient has had no recurrence of thrombophlebitis nor any abdominal symptoms referable to a mesenteric vascular lesion. Today, at the age of eighty, appearing more like an age of 70 years, he is quite healthy and active.

Discussion

In an excellent review of the literature, Grendell and Ockner[4] found that more than 50% of recurrent mesenteric venous thrombosis postoperatively had experienced previous episodes of thrombophlebitis. The presence of a hypercoagulable state was suggested, and hence a detailed evaluation of clotting factors might be indicated. Added features were the reports of two patients with migratory thrombophlebitis.[5,6] Jona et al[3] reported that 60% of recurrence developed at sites of anastomosis incurring a mortality of 37%. At the time of surgery it is vitally important that the entire thrombotic process be resected. There may be thrombosis still present in veins draining what seems to be normal bowel. Resection should include adjacent normal bowel and mesentery until all grossly thrombosed veins are encompassed.[7] It is suggested that the resected specimen be opened at the time of operation.[8] If mucosal hemorrhage is present at the margins, an additional resection is indicated. Kairaluome et al[7] cite the probability of a "second look" within the first 24 post-operative hours if a segment of intestine with questionable viability is left behind.

The second crucial point in minimizing the probability of recurrent mesenteric venous thrombosis is the use of adequate doses of heparin anticoagulant immediately postoperatively or even during the operation.[7] In a review by Naitove and Weissman,[10] eight of sixteen patients not receiving anticoagulant therapy died postoperatively (50%) while all 17 who received anticoagulant after surgery survived. They recommend seven to ten days of treatment with heparin followed by an additional ten weeks of therapy with warfarin sodium. Jona[3] maintained anticoagulant therapy in his patient for more than two years. Optimal duration of this therapy is still unknown.

This patient was fortunate to have had early operative intervention. It is the most important factor[7] in prognosis before extensive thrombosis has developed throughout the splanchnic venous circulation. Following discharge from the hospital, the vital decision to be made was the duration of anticoagulant therapy. The hazard of prophylaxis had to be weighed against the threat of recurrence of mesenteric venous occlusion. This patient had a past history and a familial history of significant acute thrombophlebitis, and he incurred an episode of primary mesenteric venous thrombosis with postoperative recurrence. Despite apparently adequate anticoagulant depoheparin and dicumarol dosage after the first operative procedure, the Lee White clotting and prothrombin times of the patient decreased to essentially normal levels. The clinical picture strongly suggested the presence of a hypercoagulable state. As an office patient he was very cooperative and his prothrombin time became quite predictable when taken once or twice monthly. Long term anticoagulant therapy appeared to be indicated.

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Methyl Methacrylate Cement Induced Pseudoaneurysm of the Right Common Femoral Artery

MARK L. KRAUS, M.D., MUNIR H. HAMZI, M.D., RICHARD A. MATZA, M.D.

AND PANCH JEYAKUMAR

Case Report

While hospitalized for an upper gastrointestinal bleed, a 54-year-old female complained of sharp pulsating right groin pain of one months duration. The pain radiated along the anterior thigh and was accentuated by standing.

The patient had a prior history of severe degenerative joint disease of the right hip, and thirteen months prior to this admission underwent a right total hip replacement. Five months prior to this admission because of an ensuing infection, a modified girdlestone procedure including removal of cement and prosthesis was performed. After five weeks of skeletal traction, intravenous antibiotics and anticoagulation therapy, an uneventful revision, right total hip replacement was performed.

Examination of the right groin revealed a pulsatile tender mass. There was a to and fro bruit over the mass. Distal pulses of the right lower extremity were reduced in amplitude from previous examination, but there was no clinical evidence of vascular compromise.

Ultra sound of the area revealed a 6x6 cm. cystic lesion with an aneurysm or A-V fistula (See Figure 1).

Selective angiography (Aorto femoral arteriography) demonstrated a 7x9 cm. pseudo aneurysm of the right common femoral artery (see Figure 2). Densities compatible with methyl methacrylate cement were noted medial to the acetabulum.

MARK L. KRAUS, M.D., Medical Director, Acute Treatment and Evaluation Unit; Internist, Department of Internal Medicine; MUNIR H. HAMZI, M.D., Attending, Department of Surgery; RICHARD A. MATZA, M.D., Attending, Department of Orthopedic Surgery; PANCH JEYAKUMAR, M.D., Resident, Department of Internal Medicine; all of St. Mary's Hospital, Waterbury, CT.

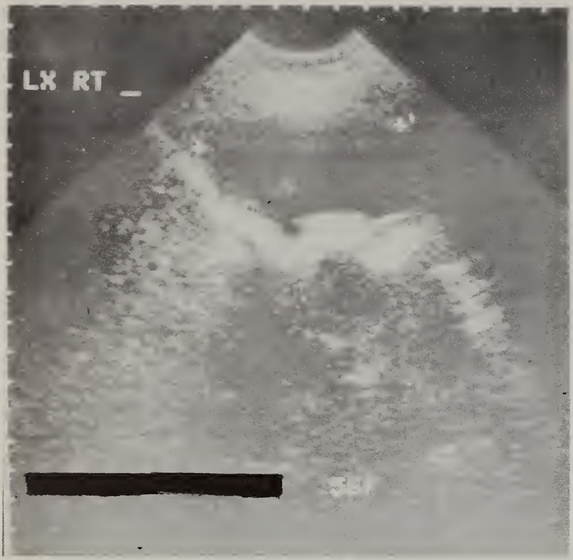

Figure 1
Ultrasound of the right groin, crosses signify aneurysm.

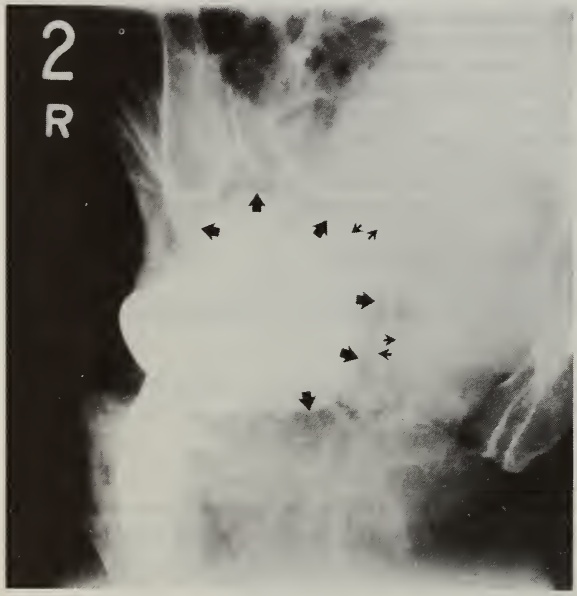

Figure 2
Selective aortofemoral arteriogram. Large arrows—aneurysm. Small arrows—right common femoral artery.

At surgery, a pseudoaneurysm of the right common femoral artery was exposed and dissected. On opening the pseudoaneurysm itself, a rent in the posterior wall of the common femoral artery was identified and associated with a sharp protrusion of methyl methacrylate cement from previous hip surgery. The right hip and prosthesis were incorporated in the pseudoaneurysm. The rent in the posterior wall of the common femoral artery, approximately 0.5 cm., was in direct contact with the methyl methacrylate protrusion (see Figure 3). The protrusion of methyl methacrylate cement was debrided with a rongeur. The pseudoaneurysm was excised and the right common femoral artery was mobilized, the ends freshened and anastomosed end to end. The gracilis muscle was interposed between the repaired artery and the hip joint. The patient's post operative period and subsequent course has been uneventful, with no evidence of infection, mechanical loosening of the right hip, or recurrence of an aneurysm or pseudoaneurysm.

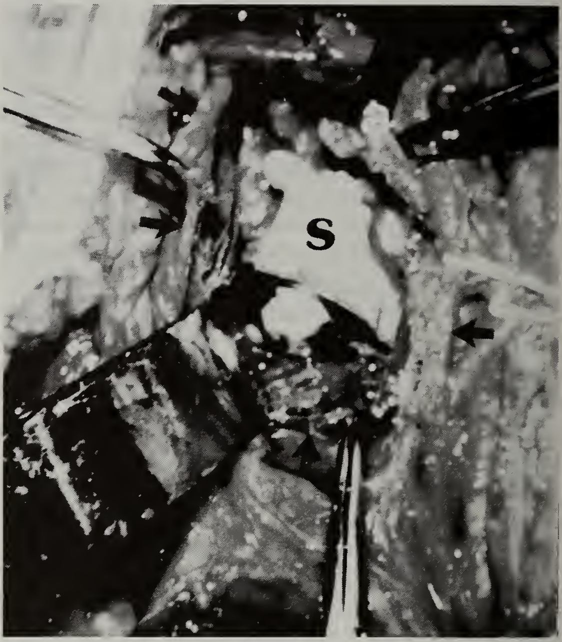

Figure 3
Picture of the methyl methacrylate cement protruding through aneurysm.

Discussion

Vascular injury is not an uncommon complication in total hip replacement (THR). The time interval between the injury to the vessel at surgery and the presentation of symptoms is dependent on the nature and the severity of the injury. Most frequently implicated factors for causing vascular injuries are: retractors, screws, cement removing instruments, and nail plates.[2,3] Rarely is methyl methacrylate cement, often used, in THR implicated in causing vascular injury.[2,4] This polymerized substance does not cause tissue reaction but on hardening can form spicules and sharp edges which can cause trauma to adjacent vessels, nerves, and tissues i.e. urinary bladder.[8] The vascular injuries associated with methyl methacrylate cement are: massive arterial hemorrhage; arterial thrombosis; hematoma formation sometimes resulting in limb ischemia; A-V fistula; and development of a false aneurysm.[2,5,6]

Ultra sound and angiography provide rapid diagnostic evaluations defining the injury. Expeditious surgical intervention with ligation of the injured vessel and/or thrombectomy angioplasty and/or direct repair of the arterial tear help to salvage the limb in question.

In our patient's case, the rent in the posterior wall of the right common femoral artery was caused by a sharp sheet-like protrusion of methyl methacrylate cement that was formed during her revision right total hip replacement surgery.

The question arises whether the artery was injured during the intra-operative course of any of the surgical procedures and not due to a gradual erosion of the artery wall by the projection of cement. This is very unlikely, since the procedures were not nearly as difficult as they could have been, and visualization and surgical exposure were never a problem during any of the cases. Debridement of the cement during the girdlestone procedure was made fascile due to the infectious process which weakened the bone-cement interface. It was not necessary to impliment the use of a cement eater or midas rex tool, which are often implicated in vascular injury during this type of surgery. In reconstructing the hip for a second time, the surgeon was concerned about getting adequate pressurization done through a posteriolateral approach, some of the methacrylate oozed between the preformed scar tissue anteriorly in the direction of the right common femoral artery. Although careful debridement of the excess bone cement was carried out, it was not until the anterior exposure to the right hip during the repair of the right common femoral artery was done, that the very thin sharp edged sheet of cement was visualized. This sharp sheet like protrusion of the cement was debrided with a ronguer and the gracilis muscle interposed between the repaired artery and the hip joint to serve as a protective bed for the freshly repaired vessel.

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WHY MALPRACTICE PANELS MAY BE AN ENDANGERED SPECIES

Add another state to the list of those having little luck with malpractice screening panels. In Massachusetts, 53% of the cases decided in favor of the defendants went to trial anyway, according to a study of claims managed by one carrier. Hospitals had the best success: Between 1981 and 1984, more than half the suits against them were decided in their favor, compared with 35% for physicians.

How medical malpractice looks to a tribunal

	1981	1982	1983	1984[1]
Decisions for the plaintiff	56.9%	68.3%	61.5%	46.2%
Decisions for the defendant	40.0	26.6	30.8	36.9
Split decisions[2]	3.1	5.1	7.7	16.9

[1] Projection based on 11 months actual. [2] When the panel ruled differently for separate defendants named in the same suit. Source: Risk Management Foundation of the Harvard Medical Institutions Inc.

—*Medical Economics*, April 15, 1985

The Development of Histiocytosis X in Patient with Hodgkin's Lymphoma

JACQUELINE M. LYON, M.D., JOHN PEZZIMENTI, M.D.
AND RAMON N. KRANWINKEL, M.D.

ABSTRACT – This report describes the development of histiocytosis X in a patient with Hodgkin's disease in complete remission. Initially, the acute symptoms and histology were attributed to relapse of Hodgkin's disease. Upon further review it became clear that the patient had multifocal histiocytosis X. Although there have been previously reported cases of histiocytosis X concurrent with or complicating Hodgkin's disease, this is the first reported case of truly multifocal histiocytosis X in a patient in remission from Hodgkin's disease. Awareness of this entity may lead to the recognition of other cases and aid in the evaluation and therapy of similar patients with lymphoma.

Introduction

Histiocytosis X is a disorder of unknown etiology first described by Lichenstein in 1953. It consists of lesions of benign proliferating Langerhans type histiocytes admixed with eosinophils and other inflammatory cells involving either the bone alone or the bone and multiple other organs. The unifocal form of the disease is characterized by solitary or multiple lytic bone lesions which usually respond to excision, radiation, steroids or resolve spontaneously. A local extraosseous presentation exists of which the best example is primary pulmonary histiocytosis X. Lastly there is the multifocal form which may be characterized by lymphadenopathy, pulmonary involvement which is often heralded by fever, cough, dyspnea, and weight loss, with lytic lesions of bone and by involvement of multiple other organs including the pituitary, cranial nerves, the eye, skin, oral cavity, kidneys, liver and female genitalia. The course of this entity is variable but in over a half of the patients there is a spontaneous remission. Those that do not spontaneously remit may respond to steroids.[2, 6, 9, 16] This report presents our experience with multifocal eosinophilic granuloma developing in a patient with Hodgkin's disease. This may cause diagnostic confusion with grave therapeutic consequences for the patient.

Case Report

A 31-year-old white male first presented to the hospital in June, 1972, with cervical and axillary lymphadenopathy. On subsequent investigations, which included an exploratory laparotomy, he was found to have Hodgkin's disease, nodular sclerosing type, Stage II A. He received extended mantle-field irradiation consisting of 4000 rads. Because of biopsy-proven recurrent disease in the right axilla, the patient received additional irradiation (3000 rads) to this area in December 1972. He however, continued to have persistent right axillary lymphadenopathy and was retreated with a third course of radiation therapy (2600 rads) in January of 1973. In addition to the radiotherapy, the patient received six courses of MVVPP combination chemotherapy for six months. The patient entered and remained in complete remission until 1981 when he relapsed with Stage IV B Hodgkin's disease as manifested by fever, weight loss, and biopsy-proven disease in the bone marrow. After combination chemotherapy, consisting of ABVD, alternating with MOPP for one year, the patient obtained a complete remission. He did well until July, 1982, at which time he developed a cough, dyspnea on exertion and bitemporal hemianopsia. A chest x-ray revealed bilateral interstitial pulmonary infiltrates; a CT scan of the brain was negative. A gallium scan demonstrated diffuse uptake of radioactivity in both lungs. An open lung biopsy was obtained and interpreted as suggestive of Hodgkin's disease. The biopsy specimen was subsequently reviewed by two other pathologists at separate institutions. One reported it as diffuse fibrosis and the second as histiocytosis X. A reevaluation of the patient in November 1982 revealed progressive bilateral pulmonary infiltrates by chest x-ray, as well as new areas of uptake in the calvarium and left anterior ribs by bone scan. Skull and rib x-rays confirmed the presence of lytic lesions in the left occiput, left frontal bone, and left anterior fifth rib. The patient underwent a bronchoscopy with transbronchial lung biopsy and bronchial alveolar lavage. The lung biopsy was consistent with pulmonary eosinophilic granuloma and the bronchial aveolar lavage revealed a predominance of IgG-positive lymphocytes and eosinophils. Biopsies of the lytic lesion of the rib as well as an inguinal lymph node were done and also revealed involvement by histiocytosis X (See Figures).

Following the establishment of the diagnosis of multifocal eosinophilic granuloma, the patient remained symptomatic with cough, dyspnea, and rib pain and his pulmonary infiltrates continued to progress as evidenced by chest x-ray. He was subsequently started on high doses of Prednisone which resulted in complete resolution of his symptoms and pulmonary infiltrates but no change in his lytic bone lesions. As of February 1984

JACQUELINE M. LYON, M.D., Resident, Department of Radiation Therapy, Hospital of the University of Pennsylvania, Philadelphia, PA. JOHN PEZZIMENTI, M.D., Attending, Department of Hematology-Oncology, Danbury Hospital; Clinical Assistant Professor of Medicine, Yale University School of Medicine. RAMON N. KRANWINKEL, M.D., Medical Director of Hematology and Blood Bank Laboratories, Danbury Hospital, Danbury, CT.

Reprint requests to: Danbury Hospital, Danbury, CT 06810 (Dr. Kranwinkel).

the patient is on no medication, is asymptomatic with no evidence of active pulmonary disease on chest x-ray and has remained well for more than one year since his initial presentation with histiocytosis X.

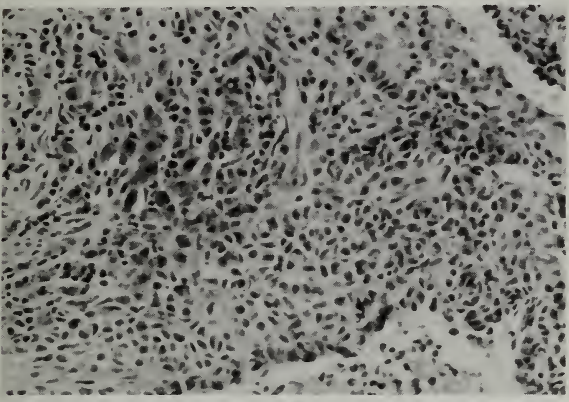

Figure 1

Lung showing cellular lesion with abundant histiocytes and eosinophils. Bronchial epithelium should be note. (X250)

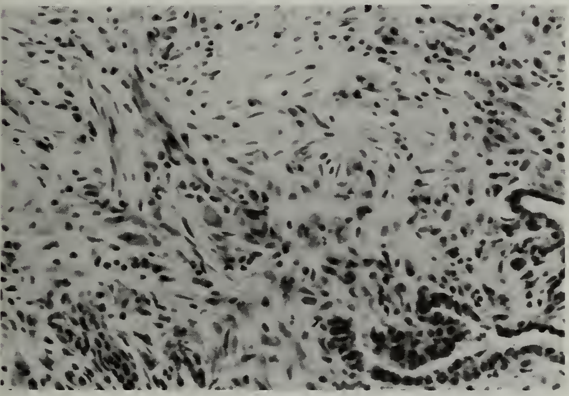

Figure 2

Lung with fibrotic lesion. Some histiocytes and eosinophils present. (X250)

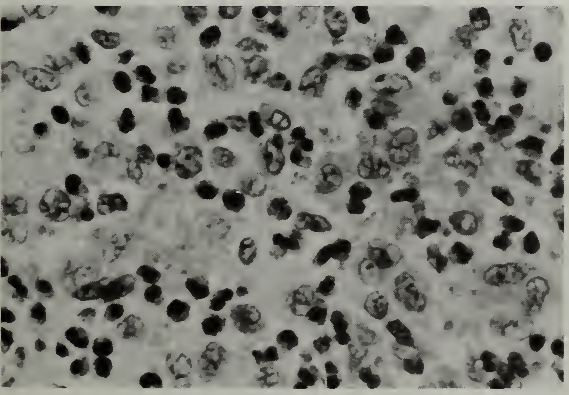

Figure 3

Rib lesion showing abundant histiocytes and eosinophils. (X600)

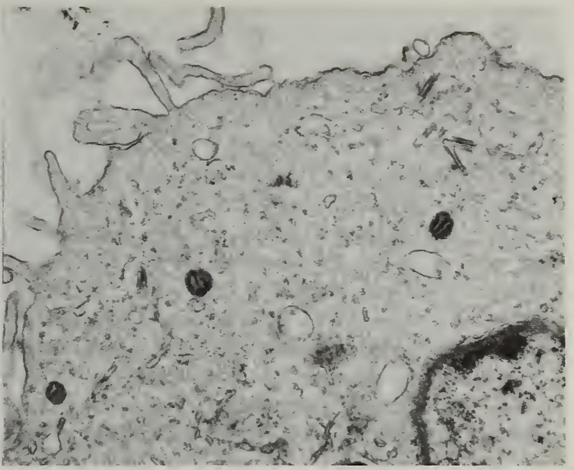

Figure 4

Electron micrograph rib lesion. Histiocyte with Langerhans granules (X35000)

Discussion

Over the past five years there have been several papers reporting the rare occurrence of histiocytosis X in patients with malignant lymphoma.[5,7,8,14,15] Kjeldsberg and Kim described six patients, three with Hodgkin's disease and three with non-Hodgkin's lymphoma, in whom lymph node biopsy specimens revealed lesions indistinguishable from eosinophilic granuloma in association with the typical histologic features of malignant lymphoma.[7] Williams and Dorfman excluded four patients (two with Hodgkin's and two with non-Hodgkin's lymphoma) from their study of 21 patients with histiocytosis X involving the lymph nodes because of the difficulty in evaluating the course of this disease in patients being treated for lymphoma.[15] In two of these cases, histiocytosis X and lymphoma were found in the same node and in another patient, a biopsy of a lytic lesion in a rib demonstrated histiocytosis X. Another patient with histiocytosis X involving the mandible and gingival mucosa reported by Frederikson and Thommesen was noted to develop one year later cervical lymphadenopathy which on biopsy revealed Hodgkin's disease.[5] L'Hoste, et al, recently reported a patient with Hodgkin's disease treated with seven cycles of MOPP and radiation who, a year after the diagnosis of his lymphoma, presented with a right rib fracture and bilateral diffuse reticulonodular pulmonary infiltrates.[8] Microscopic examination of both the lytic rib lesion and open lung biopsy, was compatible with eosinophilic granuloma. Another recent paper by Sajjad and Luna described the occurrence of primary pulmonary histiocytosis X in two patients several years after being treated for Hodgkin's disease.[14]

Finally Burns, Colby and Dorfman describe six patients in whom histiocytosis X was found in the same lymph nodes harboring malignant lymphomas (five with Hodgkin's disease and one with non-Hodgkin's lymphoma) bringing to 12 the total number of cases reported.[1] While others feel the occurrence of histiocytosis X and Hodgkin's disease may be an incidental or fortuitous happening, Burns et al point out that they have never seen Langerhans' cell granulomatosis (histiocytosis X) associated with metastatic cancer in the lymph nodes from mastectomies, radical neck dissections, or other numerous lymph node samples, and suggest that the association of histiocytosis X and Hodgkin's disease is more than a coincidence. When Colby et al reviewed 659 cases of Hodgkin's disease in a retrospective analysis they found two examples of histiocytosis X associated with Hodgkin's disease yielding a 0.3% crude incidence for the occurrence of histiocytosis X and Hodgkin's disease.[3] Our case report is, to date, the only one in which eosinophilic granuloma has been found in four different sites, namely bone, lung, lymph node, and probably brain in a patient in remission from Hodgkin's disease.

The occurrence in the same patient of eosinophilic granuloma, a disorder of abnormally proliferating benign histiocytes, and of Hodgkin's disease which may be a disorder of malignant histiocytes, is quite intriguing.[10,12,13] Because of the paucity of cases, it is difficult to make any conclusions concerning a possible common or related pathogenesis of these two diseases whose etiologies remain unknown. It may be as Kjeldsberg and Kim suggest, that the appearance of Hodgkin's lymphoma and eosinophilic granuloma in the same patient is completely fortuitous, but the increased number of reports of histiocytosis X and Hodgkin's disease occurring in the same patient raise the possibility of a distinct relationship of these two disorders.[7]

Osband et al, Sajjad and Luna offer, however, a hypothesis which is based on the well recognized observation that patients with Hodgkin's disease have defects in their cellular immunity.[4,11,14] In addition, intensive radiotherapy and chemotherapy used in the treatment of this lymphoma depresses further the patient's cellular immunity. It is, therefore, possible that this immunocompromised state, precipitated by the lymphoma and or aggressive therapy, allows for the proliferation of benign histiocytes and the subsequent development of histiocytosis X in patients with Hodgkin's as well as non-Hodgkin's lymphomas. The presence of an immunocompromised state may also lend support to the proposed infectious origin of histiocytosis X.

Whatever the possible link may be between histiocytosis X and Hodgkin's disease, it is important to realize that they may occur in the same patient and that it may be difficult sometimes to distinguish between them histologically. This problem was illustrated by the present case where the first lung biopsy was interpreted initially as suggestive of recurrent Hodgkin's disease. It was only following a second lung biopsy and the biopsy of the lytic rib lesion and lymph node that the diagnosis of multifocal eosinophilic granuloma was finally confirmed.

This distinction is obviously of major importance since the treatment and prognosis is vastly different for the two disorders.

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CONSENSUS DEVELOPMENT SUMMARIES

Lowering Blood Cholesterol to Prevent Heart Disease

NATIONAL INSTITUTES OF HEALTH

• Coronary heart disease is responsible for more than 550,000 deaths in the United States each year. It is responsible for more deaths than all forms of cancer combined. There are more than 5.4 million Americans with symptomatic coronary heart disease and a large number of others with undiagnosed coronary disease, many of them young and highly productive. It has been estimated that coronary heart disease costs the United States more than $60 billion a year in direct and indirect costs.

Coronary heart disease is caused by atherosclerois, a slowly progressive disease of the large arteries that begins early in life but rarely produces symptoms until middle age. Often the disease goes undetected until the time of the first heart attack, and this first heart attack is often fatal. Modern methods of treatment have improved greatly the outlook for patients having heart attacks, but major progress in our battle against this number 1 killer must rest on finding preventive measures.

A number of risk factors have been identified as strongly associated with coronary heart disease. Cigarette smoking, high blood pressure, and high blood cholesterol levels are the most clearly established of these factors. Risk is greater in men, increases with age, and has a strong genetic component. Obesity, diabetes mellitus, physical inactivity, and behavior pattern are also risk factors.

A large body of evidence of many kinds links elevated blood cholesterol levels to coronary heart disease. However, some doubt remains about the strength of the evidence for a cause-and-effect relationship. Questions remain regarding the exact relationship between blood cholesterol and heart attacks and the steps that should be taken to diagnose and treat elevated blood cholesterol levels.

To resolve some of these questions, the National Heart, Lung, and Blood Institute (NHLBI) and the National Institutes of Health Office of Medical Applications of Research convened a Consensus Development Conference on Lowering Blood Cholesterol to Prevent Heart Disease from Dec. 10 to 12, 1984. After hearing a series of expert presentations and reviewing all of the available data, a consensus panel of lipoprotein experts, cardiologists, primary care physicians, epidemiologists, biomedical scientists, biostatisticians, experts in preventive medicine, and lay representatives considered the evidence and agreed on answers to the following questions:

1. Is the relationship between blood cholesterol levels and coronary heart disease causal?
2. Will reduction of blood cholesterol levels help prevent coronary heart disease?
3. Under what circumstances and at what level of blood cholesterol should dietary or drug treatment be started?
4. Should an attempt be made to reduce the blood cholesterol levels of the general population?
5. What research directions should be pursued regarding the relationship between blood cholesterol and coronary heart disease?

Panel's Conclusions

Elevation of blood cholesterol levels is a major cause of coronary artery disease. It has been established beyond a reasonable doubt that lowering definitely elevated blood cholesterol levels (specifically, blood levels of low-density lipoprotein (LDL) cholesterol) will reduce the risk of heart attacks caused by coronary heart disease. This has been demonstrated most conclusively in men with elevated blood cholesterol levels, but much evidence justifies the conclusion that similar protection will be afforded to women with elevated levels. After careful review of genetic, experimental, epidemiologic, and clinical trial evidence, we recommend treatment of individuals with blood cholesterol levels above the 75th percentile (upper 25% of values). Furthermore, we are persuaded that the blood cholesterol levels of most Americans are undesirably high, in large part because of our high dietary intake of calories, saturated fat, and cholesterol. In coun-

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From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, MD.

Reprint requests to Office of Medical Applications of Research, Bldg. 1, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

tries with diets lower in these constituents, blood cholesterol levels are lower and coronary heart disease is less common. There is no doubt that appropriate changes in our diet will reduce blood cholesterol levels. Epidemiologic data and more than a dozen clinical trials allow us to predict with reasonable assurance that such a measure will afford significant protection against coronary heart disease.

For these reasons we recommend the following:

1. Individuals with *high-risk blood cholesterol levels* (values above the 90th percentile) should be treated intensively by dietary means under the guidance of a physician, dietitian, or other health professional; if response to diet is inadequate, appropriate drugs should be added to the treatment regimen. Guidelines for children are somewhat different, as discussed below.

2. Adults with *moderate-risk blood cholesterol levels* (values between the 75th and 90th percentiles) should be treated intensively by dietary means, especially if additional risk factors are present. Only a small proportion should require drug treatment.

3. All Americans (except children younger than 2 years of age) should be advised to adopt a diet that reduces total dietary fat intake from the current level of about 40% of total calories to 30% of total calories, reduces saturated fat intake to less that 10% of total calories, increases polyunsaturated fat intake but to no more than 10% of total calories, and reduces daily cholesterol intake to 250 to 300 mg or less.

4. Intake of total calories should be reduced, if necessary, to correct obesity and adjusted to maintain ideal body weight. A program of regular moderate-level exercise will be helpful in this connection.

5. In individuals with elevated blood cholesterol levels, special attention should be given to the management of other risk factors (hypertension, cigarette smoking, diabetes, and physical inactivity).

These dietary recommendations are similar to those of the American Heart Association and the Inter-Society Commission for Heart Disease Resources.

We further recommend the following:

6. New and expanded programs should be planned and initiated soon to educate physicians, other health professionals, and the public to the significance of elevated blood cholesterol levels and the importance of treating them. We recommend that the NHLBI provide the focus for development of plans for a National Cholesterol Education Program that would enlist participation by and contributions from all interested organizations at national, state, and local levels.

7. The food industry should be encouraged to continue and intensify efforts to develop and market foods that will make it easier for individuals to adhere to the recommended diets, and school food services and restaurants should serve meals consistent with these dietary recommendations.

8. Food labeling should include the specific source or sources of fat, total fat, saturated and polyunsaturated fat, and cholesterol content as well as other nutritional information. The public should be educated on how to use this information to achieve dietary aims.

9. All physicians should be encouraged to include, whenever possible, a blood cholesterol measurement on every adult patient when that patient is first seen; to ensure reliability of data, we recommend steps to improve and standardize methods for cholesterol measurement in clinical laboratories.

10. Further research should be encouraged to compare the effectiveness and safety of currently recommended diets with those of alternative diets; to study human behavior as it relates to food choices and adherence to diets; to develop more effective, better-tolerated, safer, and more economical drugs for lowering blood cholesterol levels; to assess the effectiveness of medical and surgical treatment of high blood cholesterol levels in patients with established clinical coronary artery disease; to develop more precise and sensitive noninvasive artery imaging methods; and to apply basic cell and molecular biology to increase our understanding of lipoprotein metabolism (particularly the role of high-density lipoprotein (HDL) as a protective factor) and artery wall metabolism as they relate to coronary heart disease.

11. Plans should be developed that will permit assessment of the impact of the changes recommended herein as implementation proceeds and provide the basis for changes when and where appropriate.

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1. Is the Relationship Between Blood Cholesterol Levels and Coronary Heart Disease Causal?—The evidence supporting a causal relationship between blood cholesterol levels and coronary heart disease comes from a wealth of congruent results of genetic, experimental pathologic, epidemiologic, and intervention studies. These data establish beyond any reasonable doubt the close relationship between elevated blood cholesterol levels (as measured in serum or plasma) and coronary heart disease. At the same time, it is equally clear that an elevated blood cholesterol level is not the *only* cause of coronary heart disease. Hypertension, cigarette smoking, diabetes mellitus, obesity, and physical inactivity, along with a number of other risk factors such as age, sex, and family history, are important contributing causes. There probably are other undiscovered contributing causes. However, we shall confine ourselves here primarily to a discussion of elevated blood cholesterol levels.

It is now firmly established that all cholesterol is carried in the bloodstream in several protein-lipid combinations known as lipoproteins and that most of the blood cholesterol in humans is carried by specific LDLs. Some is also present in HDLs and in very low-density lipoproteins. The LDL particles, when present in excess in the blood, are deposited in the tissues and form a major part of a buildup in the artery wall to form atherosclerotic plaque. Atherosclerosis narrows the channels of the coronary arteries, the vessels that furnish the major blood supply to the heart muscle.

Genetic Evidence

Severe coronary heart disease can result from high blood cholesterol levels in the absence of any other contributing risk factors. This is clearly demonstrated by the accelerated and clinically catastrophic coronary heart disease in children with inherited hypercholesterolemia in its most severe form. These children lack the specific receptor that normally removes LDL from the blood, and, as a result, they have very high LDL cholesterol levels from birth. They frequently suffer severe coronary heart disease, and death may occur even in childhood. Careful study of these diseased arteries reveal large quantities of cholesterol in the plaques.

The LDL receptor normally plays a critical role in regulating blood cholesterol levels in all mammals, including humans. It has been purified and fully characterized.

Studies suggest that a number of cases of clinically important coronary heart disease with less severe elevations of blood cholesterol levels may be explained by partial deficiencies of *functioning* LDL receptors, deficiencies induced by dietary and life-style factors. Thus, the basis of high blood cholesterol level in these patients is similar to that in patients with inherited hypercholesterolemia, and, while these levels are less severe, they probably have the same implications.

Experimental Pathology (Animal Model) Evidence

With improved use of the many existing animal models, a number of very important relationships between blood cholesterol, atherosclerosis, and coronary heart disease have been demonstrated:

- Many species (including several nonhuman primates) develop atherosclerosis when fed diets that raise their blood cholesterol levels.
- Studies over time demonstrate that hypercholesterolemic monkeys (and other species) develop intimal lesions that progress from fatty streaks to typical raised plaques to complicated ulcerated plaques resembling those seen in humans suffering from coronary heart disease.
- Hypercholesterolemia augments experimental atherosclerosis when arterial "injury" is present.
- Severe atherosclerosis in rhesus monkeys, usually a progressive process, regresses when the blood cholesterol level is lowered substantially for an extended period by diet or by drugs.

Animal studies thus offer strong and persuasive evidence supporting the causal relationship between blood cholesterol and atherosclerosis.

Epidemiologic Evidence

A large body of epidemiologic evidence supports the direct relationship between blood cholesterol levels and coronary heart disease:

- Comparisons among various populations throughout the world reveal a direct correlation between blood cholesterol levels and the occurrence of coronary heart disease; no population has been reported to have a high rate of coronary heart disease and low blood cholesterol levels.
- People who have migrated to another country with a higher average blood cholesterol level gradually acquire the dietary habits, blood cholesterol concentrations, and coronary heart disease rates of their new country of residence.
- Severity and frequency of raised plaques in the aorta and coronary arteries are strongly correlated with blood cholesterol levels.
- Populations experiencing severe dietary (especially fat) limitations and weight loss have been shown to have less atherosclerosis and coronary heart disease and fewer heart attacks.
- Prospective studies such as the Framingham study have shown that elevated blood cholesterol levels in healthy people predict the future occurrence of coronary heart disease.
- Evidence emerging from multiple clinical trials, reviewed in the next section, clearly indicates that lowering blood cholesterol levels in patients with hypercholesterolemia decreases the likelihood of fatal and nonfatal coronary heart disease.

Thus, the evidence obtained from genetic, experimental, epidemiologic, and clinical intervention investigations overwhelmingly supports a causal relationship between blood cholesterol levels and coronary heart disease.

2. Will Reduction of Cholesterol Levels Help Prevent Coronary Heart Disease?—Our conclusion that reduction of blood cholesterol levels *will* reduce the rate of coronary heart disease is based partly on the evidence for cause-and-effect presented above and partly on the direct evidence from clinical trials noted below.

First, metabolic ward studies establish beyond reasonable doubt three dietary maneuvers that lower blood cholesterol levels: reducing the saturated fat content, increasing the polyunsaturated fat content, and reducing the cholesterol content. Second, a number of drugs have been developed that lower blood cholesterol levels. The issue of whether these interventions also influence coronary heart disease events has been more challenging.

In previous years, more than a dozen randomized trials of the effects of fat-controlled diets or drugs have been reported. Most showed some decrease in coronary heart disease event rates in the treated group, and the dietary trials carried out by Dayton et al and by Leren et al were particularly suggestive, producing 23% and 35% reductions in the incidence of coronary heart disease. However, no study considered individually could be regarded as conclusive: the sample sizes were too small, and there were in some cases unanticipated increases in noncardiovascular deaths, although these were not statistically significant. An aggregate analysis of all unifactor blood cholesterol-lowering trials, while not revealing an effect on total mortality, does indicate that coronary heart disease rates can be reduced by reduction of blood cholesterol levels.

These findings have been extended by two recently reported randomized and blinded clinical trials of the efficacy of the cholesterol-lowering drug cholestyramine resin. One of these studies, the Lipid Research Clinics Coronary Primary Prevention Trial, showed a statistically significant 19% reduction in the combined rate of fatal and nonfatal coronary heart disease in association with a 9% decrease in blood cholesterol level. The other study, the NHLBI Type II Coronary Intervention Study, showed a reduction in the angiographic progression of coronary artery disease. In addition, a third trial (the Coronary Drug Project) has recently presented information extending the earlier published finding that the use of nicotinic acid lowers the rate of recurrent coronary heart disease by demonstrating in long-term follow-up a decrease in overall mortality.

These findings, taken in conjunction with the results of the earlier studies, permit the conclusion that reduction of blood cholesterol levels in people with relatively high initial levels will reduce the rate of coronary heart disease. The clinical trials are too limited to settle the issue of effects on overall mortality. However, the complete evidence, which includes information derived from animal, pathophysiological, metabolic, and epidemiologic studies, makes it reasonable to presume that the reduction in coronary heart disease incidence will be accompanied by a reduction in overall mortality.

The magnitude of the reduction in coronary heart disease risk can be estimated from these clinical trials; they indicate that each 1% reduction in blood cholesterol level yields approximately a 2% reduction in coronary heart disease rates. This is remarkably similar to the magnitude of the beneficial outcome predicted from observational epidemiologic studies. Thus, for example, a 5⅛ reduction in blood cholesterol level resulting from the diets recommended below should reduce coronary heart disease rates by 10%. The absolute magnitude of this benefit should be greater in patients at high risk because of existing coronary heart disease or the presence of other risk factors such as cigarette smoking and hypertension. Reductions in disease rates of as much as 50% may be achievable in patients in the high-risk-cholesterol category who adhere well to a combination of effective drug treatment and a fat-controlled diet.

3. Under What Circumstances and at What Level of Blood Cholesterol Should Dietary or Drug Treatment Be Started?

What is Hypercholesterolemia?

A precise definition of hypercholesterolemia (an abnormally high blood cholesterol level) is difficult to establish. Often, an abnormally high level of a biologic substance is considered to be that level above which is found the upper 5% of the population (the 95th percentile). However, the use of this criterion in defining "normal" values for blood cholesterol levels in the United States is unreasonable; coronary heart disease is our major cause of death because, in part at least, a large fraction of our population probably has too high a blood cholesterol level. A review of available data suggests that levels above 200 to 230 mg/dL are associated with an increased risk of developing premature coronary heart disease. It is staggering to realize that this represents about 50% of the adult population of the United States. The consensus panel has chosen to define two levels of hypercholesterolemia, both of which are associated with an increased coronary heart disease risk, and *both of which should be treated.*

High-Risk Blood Cholesterol Levels (Severe Hypercholesterolemia)

This category is defined as values at approximately the 90th percentile or above as determined by the Lipid Research Clinics Prevalence Study (see the tabulation below for guidelines). It will include individuals with hereditary forms of high blood cholesterol levels, who will require the most aggressive treatment. Withholding treatment subjects these individuals to unnecessary risk.

Moderate-Risk Blood Cholesterol Levels (Moderate Hypercholesterolemia)

This category is defined as values approximately between the 75th to 90th percentiles (see the following tabulations for guidelines). It includes large numbers of people whose elevated blood cholesterol levels are due, in part, to their diet. The intensity of treatment is guided by the clinical and family history and the presence of other risk factors predisposing to coronary heart disease.

VALUES FOR SELECTING ADULTS AT MODERATE AND HIGH RISK REQUIRING TREATMENT*

Age, yr	*Moderate Risk, mg/dL (mM)*	*High Risk, mg/dL (mM)*
20-29	>200 (5.17)	>220 (5.69)
30-39	<220 (5.69)	>240 (6.21)
≥40	>240 (6.21)	>260 (6.72)

*See special guidelines for management of children below.

How Should Adults With Hypercholesterolemia Be Treated

The presence of high-risk and moderate-risk blood cholesterol values should be confirmed by a repeated analysis. Although the initial sample may be obtained without the subject's fasting, the repeated analysis should be obtained after an overnight fast so that a valid triglyceride level also can be determined.

After the secondary causes for hypercholesterolemia (eg, hypothyroidism, nephrotic syndrome, dysproteinemias, diabetes mellitus, and obstructive liver disease) have been excluded, the primary cause should be evaluated. This includes family screening to detect the hereditary forms of elevated blood cholesterol levels and to identify other family members needing treatment. Measurement of HDL cholesterol is often helpful to determine if the elevated blood cholesterol level is due to high levels of HDL (which is associated with a *lower* risk of coronary heart disease). In addition, a low HDL cholesterol level (an independent risk factor) might guide a physician to be more aggressive in treatment of individuals with high or moderately high blood cholesterol levels.

Diet Therapy

The first step in the treatment of persons with high-risk and moderate-risk blood cholesterol levels is diet therapy and caloric restriction for weight normalization in the overweight. Weight loss may reduce blood cholesterol levels, and a moderate level of physical exercise may be helpful in this regard. The dietary approach should be to lower total fat, saturated fat, and cholesterol consumption. The following guidelines are generally consistent with those of the American Heart Association and the Atherosclerosis Study Group of the Inter-Society Commission for Heart Disease Resources. We recommend a diet composed of approximately 30% of the caloric intake from fats and no more than 250 to 300 mg of cholesterol per day. An essential consideration is a reduction of the total saturated fat intake to 10% or less of total calories. It is recommended that polyunsaturated fat intake be increased but to no more than 10% of total calories. These changes can be readily made while intake of protein, vitamins, and minerals is maintained to satisfy the Recommended Dietary Allowances of the Food and Nutrition Board of the National Research Council.

Insufficient response to this diet may necessitate further restrictions of total fat to 20% to 25% of calories, with saturated fat making up 6% to 8% of the calories. The dietary cholesterol intake should be lowered to 150 to 200 mg/day (equivalent to the American Heart Association Phase II and II diets.)

The use of diet as a primary mode of therapy requires a major effort on the part of physicians, nutritionists, dietitians, and other health professionals. Life-style changes are difficult to make without adequate instruction, motivation, and encouragement. Education of physicians, as well as the general public, as to the value of reductions in dietary saturated fat and cholesterol will assist not only in treatment of patients with high- or moderate-risk blood cholesterol levels but also in achieving the goal of reducing the blood cholesterol levels of our entire adult population to less than 200 mg/dL (<180 mg/dL in those younger than 30 years).

Drug Therapy

Drug therapy should be used only after a careful trial of diet modification using the most rigorous diet appropriate for the particular individual. Even when use of drugs seems appropriate, it is important to stress that maximal diet therapy should be continued. Several drugs, used singly or in combination, are now available. These include the bile-acid sequestrants (cholestyramine and colestipol), nicotinic acid, probucol, and the fibric acids (clofibrate and gemfibrozil). Of these, bile-acid sequestrants and nicotinic acid have been shown to reduce the incidence of coronary heart disease. Clofibrate, while effective in treating one rare familial form of lipid abnormality (type III hyperlipoproteinemia), is not recommended because it is not effective in most individuals with a high blood cholesterol level but normal triglyceride level. Moreover, an excess overall mortality was reported in the World Health Organization trial of this drug. We still do not have direct evidence for the safety of any cholesterol-lowering drugs when given over decades; therefore, drug treatment should be undertaken cautiously and its desirability should be periodically reevaluated, particularly in children.

Individuals with high-risk blood cholesterol levels (severe hypercholesterolemia), especially those with the hereditary form, may well require drug therapy in addition to dietary modification. Combined drug treatment (eg, bile-acid sequestrant plus nicotinic acid) may be particularly effective. Several combined treatment regimens are under study. Individuals with moderate-risk blood cholesterol levels will usually respond adequately to diet alone. Judgment on the decision to use drugs in such patients must be made on a case-by-case basis, taking into account family history of coronary heart disease, existing coronary disease in the individual, coexistence of other risk factors, and age of the individual.

Who Should Be Treated?

As described above, individuals with high- and moderate-risk blood cholesterol levels (>75th percentile) should be treated with diet or diet and drugs. Furthermore, it is clearly recognized that it is a goal to encourage reduction of the blood cholesterol level to approximately 180 mg/dL for adults younger than 30 years and to approximately 200 mg/dL for individuals aged 30 years or older. This is recognized as a realistic "target" level that should be possible to achieve and that would be predicted to have a beneficial effect on coronary heart disease risk. As will be discussed in the following section, it is recommended that all individuals in the population consume a diet composed of approximately 30% of the calories as fat (≤10% saturated fat) and 250 to 300 mg of cholesterol a day in an attempt to shift the blood cholesterol levels in our population toward the lower levels observed in populations having much lower rates of coronary heart disease.

Both men and women at high risk, as defined above, should be treated similarly, even though premenopausal women have an apparent protection and the onset of the disease occurs later than in men. However, as in men, the leading cause of death in women is coronary heart disease, and blood cholesterol is a risk factor. Despite the fact that direct intervention studies have not been conducted in women, there is no reason to propose a separate treatment schedule for women.

Studies are available that indicate a beneficial effect of treating high cholesterol levels in individuals with preexisting clinical disease (secondary intervention) as well as in individuals without preexisting clinical disease (primary intervention). Because of their vulnerability, patients with established disease, including particularly patients with coronary bypass grafts, should be intensively treated. It is encouraging that the progression of established lesions may be retarded by appropriate dietary and drug therapy. The same may apply to the elderly patient. While there is no direct evidence on the benefit to be expected in the elderly, and while blood cholesterol becomes less important as a risk factor in old age, dietary treatment (with due attention to ensure nutritional adequacy) may still be helpful.

Special Guidelines for Management of Children

Identifying and treating children with elevated blood cholesterol levels is a subject for special consideration. It is desirable to begin prevention in childhood because patterns of life-style are developed in childhood. The moderate-fat and moderate-cholesterol diets recommended for the population at large in this report should be suitable for all family members, including healthy children older than 2 years. For children, the diets should provide all nutrients in quantities adequate to ensure growth and development and meet energy requirements. Excessive gain in weight should be avoided. The diet may be inappropriate in children or in the elderly if they are malnourished or have special nutritional requirements. For others, the diet plan is safe and nutritionally adequate.

Children at "high-risk" should be identified primarily by carefully obtained family histories rather than routine screening. The history should include parents, grandparents, and all first-degree relatives. A family history of hypercholesterolemia or premature coronary heart disease should alert the physician to obtain at least two blood cholesterol determinations. If the blood cholesterol level in such "high-risk" children is above the 75th percentile (approximately 170 mg/dL for children aged 2 to 19 years), total and HDL cholesterol measurements should be obtained. Those children with blood cholesterol levels between the 75th and 90th percentile (170 to 185 mg/dL should be counseled regarding diet and other cardiovascular risk factors and then followed up at one-year intervals. Those with levels above the 90th percentile (>185 mg/dL) require special dietary instruction and close supervision with evaluation of other risk factors. A child with a blood cholesterol level above the 95th percentile (>200 mg/dL) on two occasions is in a special category and may have one of the hereditary hypercholesterolemias. Strict dietary intervention is indicated and will be sufficient for many children. Nonresponders should be considered for treatment with a lipid-lowering agent, eg, a bile-acid sequestrant (such as cholestyramine). All family members should be screened.

Dietary management of children with elevated blood cholesterol levels should be part of total management that includes regular exercise programs, maintenance of ideal weight, avoidance of excess salt, and avoidance of cigarette smoking.

What Screening Strategy Should Be Adopted for Finding Subjects With High Blood Cholesterol Levels?

According to data from the National Center for Health Statistics, a high percentage of the American population sees a physician at least once every year. If a cholesterol level were determined in adults at these visits, many of the individuals with cholesterol levels above the 75th percentile would be identified in a relatively short time and should be evaluated and treated as described above. This physician- and clinic-oriented method for screening would be cost-effective. Obviously, some patients may not see a physician for several years, and it would be advisable to educate the public to the importance of knowing one's cholesterol level. In children, only a "family history screening" is recommended, that is, cholesterol levels should be obtained in those at higher risk because of a strong family history, as discussed above. Educational programs developed by voluntary and public health organizations in conjunction with the National Cholesterol Education Program of the NHLBI, as recommended by this consensus panel, should alert all adults to the advisability of learning their cholesterol level.

While we are not at this time recommending mass screening, a feasibility study of various screening methods in adults should be considered. Screening necessitates the availability of laboratories capable of determining precisely and accurately the blood cholesterol and HDL cholesterol levels and of physicians willing and able to manage large numbers of new patients. Thus, preliminary steps are needed before mass screening can be considered.

4. Should an Attempt Be Made to Reduce the Blood Cholesterol Levels of the General Population?

Rationale for Recommendations to the General Population

Many compelling lines of evidence link blood cholesterol to coronary heart disease. There is also strong evidence from epidemiologic studies that the relationship between level of cholesterol and level of risk for coronary heart disease covers virtually the entire cholesterol distribution for the US population. In fact, recent epidemiologic studies suggest that the relationship holds even at the lower end of the spectrum of cholesterol levels found in our population.

The Japanese population, in comparison with the US population, is characterized by a much lower average cholesterol level and a much lower frequency of coronary heart disease. The Finnish, on the other hand, have a much higher average cholesterol level and a much greater risk of coronary heart disease than do US citizens. Furthermore, Japanese who have migrated to Hawaii and to San

Francisco have higher cholesterol levels and a higher risk of coronary heart disease than nonmigrants. Compilation of all the available data suggests that it will be beneficial to lower the blood cholesterol of the average American.

In recent years, Americans have been changing their habitual diet in the direction we recommend, that is, by reducing their intake of total fat, saturated fat, and cholesterol and by increasing intake of polyunsaturated fat. This has been accompanied by a substantial reduction in the average blood cholesterol level of the population. In addition, all-cause mortality, cardiovascular mortality, and coronary heart disease mortality have also decreased, but it is difficult to determine with certainty how much, if any, of this decrease is due to changes in diet, blood pressure and cigarette usage or improved medical care. It is hoped that improved surveillance systems will clarify these issues.

Recommendations

In the general population, the basic intervention should be based on diet rather than drugs. We recommend a shift from the current typical American diet to one that is lower in total fat, saturated fat, and cholesterol. Diets with these characteristics are the usual diets consumed in a number of other countries, eg, Japan and Greece. Life expectancy in these two countries is, at virtually every age, greater than that in the United States. This applies also to the life expectancy in middle age, when mortality from coronary heart disease begins to rise sharply.

The evidence justifies for men, women, and children aged 2 years and older the reduction of calories from fat from the present average level of 40% to 30%, calories from saturated fat to 10% or less, and dietary cholesterol to no more than 250 to 300 mg daily. We recommend that calories from polyunsaturated fat be increased but not exceed 10% of total calories. This diet is generally consistent with the most recent recommendations of the American Heart Association and the Atherosclerosis Study Group of the Inter-Society Commission on Heart Disease Resources. Equally important, individuals, health professionals, and health agencies must recognize the need to control obesity both to aid in controlling blood cholesterol levels and to reduce the other health risks of obesity. Other elements important in the prevention of cardiovascular disease, including avoidance of cigarettes, control of high blood pressure, and maintenance of reasonable levels of physical activity are recommended.

Means of Implementing Dietary Recommendations in the General Population

- If dietary intervention in the general population is to be effective, the eating habits of the entire family must be changed. Thus, the recommended diet should be available to all family members except those younger than 2 years.

- Educational services that enable adults and children to make informed choices concerning their eating habits should be readily available, including ready availability of data on composition of natural and processed foods.

- Professional educational programs for physicians, dietitians, and other health professionals should be expanded to include adequate material on diet and heart disease.

- Specific food items consistent with the recommended diet should be available, accessible, and affordable.

- The food industry should accelerate its current efforts to develop, produce, and market leaner meats and other foods, including dairy products, with reduced total fat, saturated fat, and cholesterol content.

- Restaurants, including fast-food outlets, should make foods satisfying these diet recommendations available to their customers.

- Government and school food programs should serve meals consistent with these recommendations.

- Food labeling should include total calories, fat source and total fat, saturated fat, polyunsaturated fat, and cholesterol content as well as other essential nutritional information. If necessary, appropriate statutory or other changes to require such labeling should be seriously considered.

- A national cholesterol education program should be implemented for physicians, other health professionals (including those in training), and the public; its effectiveness should be periodically evaluated.

5. What Research Directions Should Be Pursued on the Relationship Between Cholesterol and Heart Disease?—We know that blood cholesterol is causally related to coronary heart disease and that the atherosclerotic process can be influenced by intervention. However, much about lipid metabolish and about the mechanisms of the atherosclerotic process remains unknown.

- *Cellular and Molecular Biology.*—A better understanding of lipoprotein production and removal, lipoprotein receptors, and apolipoproteins is needed. More information is needed with regard to factors controlling the level of HDL and its role in preventing coronary heart disease. To learn whether diets very high in polyunsaturated fatty acids have any adverse effects, more information is needed regarding their biochemical and biologic effects, including those of the highly unsaturated fatty acids found in fish oils. Research is also needed on the biology of vessel wall injury, on the cells that participate in atherosclerosis, and on the events that trigger thrombosis in atherosclerotic vessels.

- *Clinical Investigation.*—Precisely defined diets and pharmacologic interventions to reduce blood cholesterol and other lipids must be studied in individuals under carefully controlled conditions. Research on the effectiveness of regimens to lower blood cholesterol levels and to influence atherosclerosis, including surgical intervention, should also be conducted. Evaluation of these may involve atherosclerotic plaque measurement using safe, precise imaging techniques such as ultrasound, regional radioscintigraphy, magnetic resonance, and/or computer-enhanced radiography.

- *Pharmacologic Research.* —New compounds that are more effective, economical, and safe for the reduction of blood cholesterol levels are needed. Development of improved, more palatable, and less expensive bile-acid sequestrants also is needed. Similarly, a search for pharmacologic agents that would favorably influence other elements of the atherosclerotic process is highly desirable.
- *Food Product Research.* —The interface of human nutrition and human disease requires collaborative efforts within the agricultural, industrial, and health research communities. More food products that are high in nutritional quality and taste yet low in fat and cholesterol need to be developed.
- *Research in Human Behavior.* —Study of how people choose their diets and how food habits can be improved are necessary. Studies designed to measure and enhance adherence to new nutritional behaviors and treatment programs are needed.
- *Epidemiologic Investigation.* —The search for additional factors that initiate or affect the atherosclerotic process must be continued along with further studies of risk factors in major population subgroups, including blacks. As nutritional practices of the population change and as health professionals improve management of elevated blood cholesterol levels, ongoing monitoring of nutritional patterns, blood cholesterol levels, and disease and death outcomes is essential. An important corollary will be monitoring to assess disease incidence, prevalence, and case fatality rates. Research to assess the effects of blood cholesterol reduction on cardiovascular and all-cause mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated.
- *Secondary Prevention.* —The effectiveness of lowering blood cholesterol levels by medical or surgical intervention to retard or reverse atherosclerotic lesions in arteries or bypass grafts of patients with established coronary heart disease requires further investigation.
- *Community Applications.* —Community demostration research to test the effectiveness of nutrition-educational programs that influence food choices and other risk-factor behaviors of the healthy free-living population is needed.

Members of the Consensus Development Panel were Daniel Steinberg, M.D., Ph.D. (chairman), La Jolla, CA; Sidney Blumenthal, M.D., New York; Richard A. Carleton, M.D., Pawtucket, RI; Nancy H. Chasen, A.B., J.D., Bethesda, MD; James E. Dalen, M.D., M.P.H., Worcester, MA; John T. Fitzpatrick, Fairfield, CT; Stephen B. Hulley, M.D., M.P.H., San Francisco; Robert W. Mahley, M.D., Ph.D., San Francisco; Gregory O'Keefe III, M.D., Vinalhaven, ME; Richard D. Remington, Ph.D., Iowa City; Elijah Saunders, M.D., Baltimore; Robert E. Shank, M.D., St. Louis; Arthur A. Spector, M.D., Iowa City; Robert W. Wissler, M.D., Ph.D., Chicago.

Members of the Planning Committee were Basil M. Rifkind, M.D., F.R.C.P. (chairman), Bethesda, MD; Susan Clark, Bethesda, MD; Charles Glueck, M.D., Cincinnati; William Hazzard, M.D., Baltimore; Kenneth Lippel, Ph.D., Bethesda, MD; Albert Oberman, M.D., Birmingham, AL; Michael J. Bernstein, Bethesda, MD; Larry Blaser, Bethesda, MD.

The conference was sponsored by the National Heart, Lung, and Blood Institute, Claude Lenfant, M.D., director; and the office of Medical Applications of Research, Itzhak Jacoby, Ph.D., acting director.

FINAL 'BABY DOE' RULES PUBLISHED

The Department of Health and Human Services published final rules governing cases of severely handicapped infants on April 15. The "Baby Doe" regulations, effective 30 days after publication, state that physicians and hospitals must provide necessary treatment for severely handicapped infants unless death appears inevitable. But the rules specify three situations in which medical treatment may be withheld: Irreversible coma; when threatment would only prolong inevitable death; and when treatment would be so extreme and so likely to be futile that administering it would be inhuman. The regulations require that states implement them by October 9 to qualify for child abuse prevention grants from the federal government. The state program must include coordination with hospitals, effective investigation procedures, and court ordered treatment if necessary.

DNR Procedures: Purple Dots Revisited

GRAND JURY OF THE SUPREME COURT
OF THE STATE OF NEW YORK, QUEENS COUNTY

Introduction

WE, THE SPECIAL JANUARY THIRD ADDITIONAL 1983 GRAND JURY, in and for the County of Queens, pursuant to section 190.85, subdivision 1(c) of the Criminal Procedure Law, hereby submit this report of stated findings, and based thereon, propose recommendations for legislative, administrative and executive action in the public interest.

Our recommendations call for the State of New York to recognize and regulate the process by which physicians, usually in a hospital setting, determine and direct that certain terminally ill patients should not be artificially resuscitated in the event of cardiac arrest. Such a direction is generally expressed in the form of a "do not resuscitate" (DNR) or "no-code" order.

The need to decide whether to resuscitate a patient is a recent phenomenon. Twenty-five years ago, a patient whose heart stopped beating inevitably lost breathing, and then brain, functions and died. But modern medical research has demonstrated that circulation can, in what is still a relatively small number of cases, be successfully maintained by external cardiac massage while the beating of the heart is restored through pharmacological, electrical, or manual means. The resuscitation procedure itself is fairly straightforward and is in widespread use. Unfortunately, the technology available to forestall death has developed faster than the ability to treat its causes.

Because cardiac arrest occurs at some point in the dying process of every person, whatever the underlying cause, the decision to attempt resuscitation is potentially relevant for all patients. For example, a child who has been pulled from a lake after nearly drowning may be revived through prompt cardiopulmonary resuscitation and, if the blood supply to his brain was not interrupted for more than a few minutes, he can go on to live a long and healthy life with no adverse affects whatever. Any physician who did not attempt cardiopulmonary resuscitation in that situation would be regarded as seriously derelict by his peers. On the other end of the spectrum is the hopelessly terminal cancer patient whose expressed desire is for a dignified death. Repeatedly restarting his heart after each cardiac arrest would simply add a few minutes or days or weeks of suffering, and most physicians would consider resuscitation inappropriate in such a case.

We recognize that the law does not require physicians or hospitals to treat all patients alike, and we do not propose that it do so. Nor do we seek to define for doctors and their patients the appropriate circumstances in which to administer or withhold cardiopulmonary resuscitation. We do, however, urge the State to insure that the decision-making process is governed by explicit procedural safeguards to prevent the decision from being made carelessly, unilaterally or anonymously. The minimum safeguards which we recommend in this report are designed to insure, and to permit verification, that the decision not to resuscitate a patient is made only after a qualified physician has, with a reasonable degree of medical certainty, diagnosed an illness which would imminently and inevitably lead to death; has discussed the consequences of prolonging the dying process with the patient or a member of his family or other surrogate and secured his knowing and informed consent; and has permanently recorded the decision on the patient's medical chart subject, of course, to revocation.

Our concern over abuses in the DNR decision-making process was precipitated by the death of a certain elderly patient in the intensive care unit of a Queens hospital in 1981.[1] This patient's underlying illness was never definitively diagnosed, and neither she nor any member of her family was ever apprised that an order to withhold resuscitation had been contemplated or given. Nevertheless, a medical student, who may or may not have been acting on the instruction of a cardiologist, ceased to administer cardiopulmonary resuscitation himself and, according to

REPORT OF THE SPECIAL JANUARY THIRD ADDITIONAL 1983 GRAND JURY CONCERNING "DO NOT RESUSCITATE" PROCEDURES AT A CERTAIN HOSPITAL IN QUEENS COUNTY the nurses present, prevented them from calling the emergency code which would have summoned a special team of medical personnel to do so.

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[1] We have not identified the individuals or institution involved in this investigation out of respect for the privacy of the deceased patients and the constraints of Criminal Procedure Law section 190.85, subdivision 2(b), as it bears on those as to whom this report may be deemed critical.

We found that the failure to put "no-code" orders into writing was the rule, not the exception, at this hospital. In order to avoid legal responsibility for such decisions, and for no other reason, hospital officials categorically prohibited any written mention of such orders on the patients' charts. Instead, they instituted a process of designating "no-code" patients by affixing so-called "purple dots" to file cards which were kept solely by the nurses and only until the particular patient died or was discharged, and which were not routinely seen by the physicians. As a result, the "no-code" order could never be attributed to any physician and the only record of it would disappear after it was carried out. Members of the hospital administration insisted, both at the time the procedure was initiated and in their testimony before the grand jury, that the prohibition against writing such orders was justified by uncertainty over the legality of "no-coding."

We found that this "purple dot" system virtually eliminated professional accountability, invited clerical error, and discouraged physicians from obtaining informed consent from the patient or his family. We do not accept the proposition that doubts about the legality of the "no-code" decisions justified making them in secret. At the same time, we have found that some of those doubts are shared by highly responsible members of the medical profession despite virtually universal agreement that such decisions are medically appropriate in certain limited cases. Again, without seeking to prescribe specific criteria for the difficult ethical and medical decisions which must ultimately be made by dying patients and their physicians within existing legal parameters, we strongly recommend that the State expressly acknowledge that DNR decisions are regularly made as a matter of medical necessity and recognize the prevailing legal view that carrying out such a decision does not, in and of itself, constitute a violation of the civil or criminal law. Only then, we believe, can the State legitimately and effectively call upon responsible physicians and hospitals to eliminate the kind of shocking procedural abuses we have found.

THE GRAND JURY'S FINDINGS

Part I: The Death of Maria M.

On January 11, 1981, seventy-eight-year-old Maria M. took ill with what appeared to her daughter to be a flu. Because Mrs. M.'s family physician was on vacation, she was brought to the emergency room of a local hospital. Based on a diagnosis of myelophthisis, atrophy of the spinal cord, the emergency room physician decided to admit her as a hospital patient.

Within two weeks, Mrs. M. also began showing difficulty breathing and was transferred to the intensive care unit. The physicians on the staff of the hospital, and there were several involved, were never able to ascertain the cause of that condition, but they recommended a tracheostomy, which would involve an incision in the throat so that Mrs. M. could be inhalated through a mechanical respirator. Her daughter consented to the operation, and it was performed on February 11, 1981.

The operation was, in the words of one of the hospital's inhalation therapists, a "very bad job." The incision was larger than necessary to insert the tracheostomy tube which connected Mrs. M. to the respirator, and the resulting gap was patched with gauze and cotton. A second operation, to visually examine the bronchial tubes and to insert a wider tracheostomy tube, was performed on March 18. Less than a week later, the staff physicians obtained the family's consent to perform a third operation, a gastrostomy, which would allow Mrs. M. to be fed, through tubes, directly into the stomach so that food would not pass into her lungs through a fistula which had developed in her throat.

Mrs. M.'s medical chart revealed no definitive diagnosis as to the cause of her breathing difficulty, and none of the physicians who testified was able to attribute it to any terminal illness.[2] No one ever suggested to Mrs. M. or any of the members of her family who visited her regularly that cardiopulmonary resuscitation or any other life-sustaining procedures might be withheld.

Mrs. M.'s views on the subject cannot, of course, be conclusively determined. But she was coherent, and able to communicate with her daughter by writing notes and with the nurses by speaking for brief periods when the respirator was detached. When she wrote to her daughter, Mrs. M. expressed her eagerness to return home and, if necessary, to acquire her own respirator for that purpose. On the other hand, she often became agitated and on several occasions disconnected the tubing attaching her to the respirator, thereby triggering a loud alarm which alerted the nurses to reattach the tubing before any harm was done. One of the nurses, who at various times heard Mrs. M. say both that she wanted to go home and wanted to die, thought that she was disconnecting the tubing deliberately because she did not want to live. Another nurse thought that it was simply the result of fidgeting. Mrs. M. did not communicate with her daughter when she came to visit on the evening of March 26, 1981, but her daughter thought that she appeared much improved, an observation confirmed by a member of the nursing staff. It was to be the last night of Mrs. M.'s life.

At about 1:00 a.m. on March 27, the telemetry monitor at the nurses' station, which kept track of Mrs. M.'s heart beat, showed that it had slowed to sixty beats per minute, a condition known as bradycardia. The nurse who noticed this reading immediately summoned a medical student who was on duty in the intensive care unit.[3] Both responded to Mrs. M.'s room. Each saw that Mrs. M. had again become detached from her respirator. In addition, the disconnected tube had been tucked behind and up under her pillow and the alarm switch for the respirator had been turned off.

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[2] The admitting diagnosis of myelophthisis was never confirmed or treated.

[3] Hospital protocol required at least one fully licensed physician to be on duty somewhere in the hospital during the nighttime hours. However, neither he nor the resident assigned to the intensive care unit, who had been graduated from medical school but not licensed to practice in New York, was available to respond to this emergency.

The medical student began administering closed chest massage while the nurse reconnected the tubing. Another nurse arrived and asked the student whether she should call a "Code 33" emergency, the hospital's signal for all available personnel to respond and administer cardiopulmonary resuscitation and any necessary ancillary services. As the nurse started to do so, the student indicated that Mrs. M. was not to be coded. According to the testimony of both nurses, the medical student said, "What am I doing? She's a no-code," and then ceased the cardiac massage.

The medical student first testified that he could not recall "no coding" being mentioned during the incident. He later changed his testimony, asserting that someone – in "all the confusion" he did not know who–had asked him whether Mrs. M. was a "no-code," to which he responded, "A no-code? Not as far as I know at all." The student testified that the reason he did not affirmatively direct that a "Code 33" be called was that he had summoned assistance from the resident assigned to the intensive care unit and he believed that the situation could be handled by the two of them without any additional help. He also stated that Atropine and at least one other drug were administered, a fact which neither nurse recalled and which is not documented on any of the charts.

The resident testified that the call which he received from the student was not to aid in saving Mrs. M.'s life, but "to pronounce [her] dead." When the resident arrived at the intensive care unit a few minutes later, the student was out in the hall. Upon entering Mrs. M.'s room, the resident discovered that her heart was still beating, although by then quite faintly. He made a desperate effort to revive her, but did not succeed.

The resident and the medical student described the circumstances of Mrs. M.'s death to one of the two senior residents who came on duty the next morning. After hearing the facts, the senior resident rebuked the student for his failure to summon help and to continue resuscitation until it arrived. When he repeatedly demanded an explanation as to why a "code" was not called, the student remained silent. Neither resident questioned the nurses in any detail and therefore never heard their description of what the student said and did. One of the nurses, however, subsequently asked the student why he treated Mrs. M. as a "no-code" and he answered that the order to do so had been transmitted to him orally by a cardiologist.

The cardiologist was also called to testify before the grand jury, but denied leaving such an order in this or any other case. He explained that while he had, on occasion, made an on-the-spot decision to cease resuscitating a patient where he did not believe it to be medically sound to continue, he never left standing orders which would bar another physician from calling a "Code 33." The nurse in charge of the intensive care unit also stated that advance determinations of that sort were not made as to patients in that unit, because the concept of receiving intensive care was inconsistent with a diagnosis of terminal illness.

The medical student notified Mrs. M.'s family of her death, and he asked her daughter to come in to speak with doctors in the intensive care unit. When she did so, the doctors assured her that they had done "everything they could do" for her mother and sought permission to perform an autopsy. Mrs. M.'s daughter refused. A few nights later, she received an anonymous phone call from someone identifying herself as a nurse employed at the hospital and apprising her that her mother had died "unnecessarily" because "a no-code was sent out."

Pursuant to a court order secured on behalf of the grand jury, an autopsy was ultimately performed on Mrs. M.'s body. The Chief Medical Examiner of the City of New York found the cause of death to be "cardiac arrest following disconnection from the respirator." Although responsibility for that disconnection cannot be determined, the credible evidence is inconsistent with any notion that Mrs. M. committed suicide. To do so, she would have had to flip the alarm switch while still connected to the respirator. Her physical size and frail condition, the distance involved, and the barrier posed by the bed rails precludes such a feat. In addition, she would then have had to disconnect the respirator tube and neatly tuck it up behind and under her pillow. In short, we found no evidence to suggest that Mrs. M. intentionally sought to take her own life on March 27, 1981.

Part II: No coding and "Purple Dots"

In the course of our inquiry into Mrs. M.'s death, it became clear that the confusion concerning her DNR status was the direct result of a deliberate hospital policy to avoid leaving any tangible evidence of "no-code" orders. The express purpose of this policy was to insulate the institution and its medical staff from any legal consequences which might flow from their action or inaction. It became readily apparent that this institutionalized practice, and its compromising effect on a life-and-death decision-making process which could potentially affect hundreds of patients, presented a problem which transcended even the tragedy of Mrs. M.'s death.

As early as June of 1979, over a year-and-a-half before Mrs. M. died, a committee comprised of the hospital's top medical and nursing personnel, under the chairmanship of its director of medicine, formally discussed whether notes should be kept to reveal which patients "should not be coded." The minutes of that meeting reflect an awareness that coding was a problem which faced "hospitals around the country" and a particular concern with protecting the hospital staff "where litigation was involved." The committee resolved to turn to the hospital's insurance company and to lawyers employed by its "risk management consultant" for advice. The chief of surgery, meanwhile, proposed that "a color-coded tag could be placed on these charts which would indicate that a code should not be called." The minutes go on to state that: "Administration will review this procedure with nursing."

When the same committee met a month later, the executive vice-president of the hospital was present. According to the minutes, he "reported that he has reviewed the recent literature regarding written orders for coding terminally ill patients and he again requested that no formal note be entered in the charts." The executive vice-president was an attorney, not a physician, and the testimony confirms that his request was intended solely to minimize legal exposure. No medical or ethical justification for not putting "no-code" orders into written form was ever suggested. It was also clear that this "request" was not optional. As one internal memorandum instructed: "Written no-code orders are of doubtful legality and are, therefore, not permitted."

An inhalation therapist, according to the minutes of this meeting, then suggested "writing out these orders on the nurses plan. It was pointed out that these plans are discarded after the patient leaves the hospital and they are not always available. Removable color coded tags were again discussed."

Although the specific proposal for color-coded tags was nominally tabled at this meeting, the associate director of nursing, who was present at both meetings, thereafter initiated the distribution of "purple dots"—small, colored, commercially available, adhesive-backed paper discs—which she and other supervisors instructed the nurses to attach to the "Kardex" file of patients whom the doctors orally designated as not to be "coded." These files, essentially large index cards, were the sole responsibility of the nursing staff and thus the "purple dot" could not be attributed to either the physician who gave the order or the one who carried it out. In addition, the cards were routinely discarded after the patient died, and therefore no record of the decision would be available after its implementation.

Many of the nurses were deeply concerned over the absence of any institutional DNR standards, noting, for example, that a doctor on the day shift might want a patient "coded" while a doctor on the night shift—who, as in Mrs. M.'s case, might not even be a licensed physician—would decide to treat the same patient as a "no-code." There was no review; procedure and no formal method by which a "no-code" order could be revoked if the patient went into remission. The policy of the hospital, according to the testimony of the chief of surgery, was "not to have a policy," other than anonymity.

There was also no officially formulated policy which required physicians to obtain consent from, or even inform, the patient or his family before the "no-code" order was given. The chief of surgery could only describe a general practice at the hospital of communicating with every patient's family "as much as possible." Because of the lack of documentation, it is impossible to determine to what extent, if any, explicit discussions of "no-coding" were held, or with whom, but it is clear that the practice was ad hoc and that Mrs. M.'s family, for one, was never consulted. The failure to uniformly involve patients and their families in the DNR decision-making process was the logical consequence of the standing policy not to leave evidence which might be used against the hospital in a law suit.

Some of the nursing staff also criticized the "purple dot" system as an unreliable method of transmitting "no-code" orders. One complaint was that the system was not secure: the dots could be readily purchased, or even just picked up off a desk: and many people, including the television concessionaire, had access to the nurses' "Kardex." Some of the nurses also feared that the dots could be put on the wrong card, or dislodge and stick onto a different card, and reports of similar errors had circulated among the nurses.

This potential danger was illustrated by the "Kardex" of a Medicaid patient named Daisy S., who died at the hospital on January 5, 1982. The card, which was preserved by a nurse, had two purple dots affixed to it. The grand jury was not able to determine the origin of either dot because all of the doctors who were significantly involved in treating Mrs. S. denied any knowledge of these dots. They were also divided over whether she even had any condition which was necessarily terminal. The nurses could not attribute the "no-code" designation to anyone. The testimony presents no reasonable explanation why any patient would have been intentionally "no-coded" more than once. If the second dot was placed or fell on Mrs. S.'s "Kardex" by accident, it could have just as readily ended up on the file of some other patient who would otherwise be resuscitated.[4]

One other aspect of the DNR system at this hospital that was particularly troublesome to the nurses was the fact that they were responsible for documenting the decisions which the doctors were unwilling to put in writing. As the testimony of Daisy S.'s physicians vividly demonstrated, the doctors were able to deny any knowledge of questionable "purple dot" orders. If anyone was to be held accountable, it would very likely be the nurses who actually put the dots on the files. The potential for shifting blame on that basis was highlighted by the testimony of the chief of surgery – the original proponent of the color-coding system – who told the grand jury that the oral "no-code" directives issued by the physicians were nothing more than "suggestions, if you will, to the nurse . . . [who] is perfectly at liberty to call in the code if she desires to call in the code."

This latter statement is not consistent with the weight of the credible testimony of the nurses and other physicians concerning standard hospital protocol. For example, nurses were not even permitted to dispense aspirin without the permission of a physician. The nurses at Maria M.'s bedside who did not call in a "Code 33" were following what they reasonably perceived as the order of the student whom the hospital left in charge of making medical decisions. They cannot in fairness be criticized for not overruling their superior, especially where hospital policy made it impossible for them to authoritatively determine, then or ever, whether a responsible, licensed physician had ever left a DNR order, let alone why it was made or with whose consent.

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[4] The occasion to resuscitate Mrs. S. did not arise. She was found dead, apparently from sepsis, a blood infection, when a nurse entered her room during routine rounds.

Part III: The State's duty to recognize and address the DNR issue.

In March of 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research published a lengthy report entitled, "Deciding to Forego Life-Sustaining Treatment." The report does not remotely support concealing or distorting the responsibility for decisions not to resuscitate patients, but it does confirm that the medical profession is legitimately concerned about the legality of such decisions. Both the report, and a commission consultant who testified before this grand jury, have emphasized that the absence of explicit legal recognition of "do not resuscitate" orders as a valid medical option discourages many physicians from giving them, despite the fact that they are almost universally regarded within the profession as medically and ethically justified under carefully limited circumstances.

This uncertainty as to the legality of DNR orders was described by the consultant as particularly acute in New York, attributable in part to the prevalence of civil litigation and in part to the broad discretion vested in dozens of independent local prosecutors. He further suggested that this grand jury was "part of the problem" because of the erroneous perception that this investigation was initiated, in the words of the President's Commission, because the "Attorney General's Office disapproved DNR orders being written for elderly, incompetent patients." President's Commission Report at 238.

The President's Commission did not propose specific legislation or rules. Rather, it cited with approval the growing number of hospitals and medical societies which, in one case in consultation with a local bar association, are currently codifying and improving the way in which decisions not to resuscitate are reached. The Commission essentially concluded that so long as the operative standards reflect the appropriate values – recognition of the patient's right to self-determination; medical commitment to maximizing the patient's physical well-being; and equity among patients similarly situated – the decision-making process will operate best without legislative constraints or judicial second-guessing. That conclusion, however, is premised upon hospitals having "an explicit policy on the practice of writing and implementing DNR orders. In the absence of an established mechanism, decision-making might fail to meet the requirements of informed consent or the responsibility for making and carrying out the decision might be assigned to an inappropriate person." *Id.* at 248-49.

We have found that the established mechanism, at least at this Queens hospital, not only failed to satisfy those basic concerns but actively subverted them by discouraging discussion and diffusing accountability. It is that finding which leads us to recommend State-imposed safeguards for the decision-making process.

We believe that the State, without prescribing or second-guessing medical or ethical judgments in individual cases, can and should establish such procedural safeguards. The federal government has recently promulgated DNR guidelines for the 172 medical centers operated by the Veterans Administration and the 12,000 physicians, 30,000 registered nurses and 30,000 aides and licensed practical nurses employed by it throughout the country. The premise of the Veterans Administration guidelines is that while the essential function of a hospital is to save lives, there are, in the case of a terminal illness, legitimate medical and humanitarian decisions which can be made concerning the moment and mode of death, especially when the patient asks that his suffering not be prolonged unnecessarily. The specific protocols are left to individual facilities or regional groups, but each is required to promulgate general policy standards and definitions of terminal illnesses; to take cognizance of the wishes of the patient, or, if he is incompetent, of his family or other surrogate; and, most specifically, to assure that if a "do not resuscitate" decision is reached, "the order *must be written* into the patient's medical record by the attending physician, rather than a house officer or resident" (emphasis in original). The full text is annexed to this report as Appendix I.

The New York State Medical Society has developed similar guidelines concerning the decision not to resuscitate. They are not binding, but are designed to encourage hospital medical staffs and governing bodies to be sure that the determination is made by an attending physician, after discussion with appropriate supervisory members of the hospital staff, and based upon sufficient knowledge as to the seriousness of the patient's medical condition. These guidelines provide that if a patient is capable of making a judgment, the decision not to resuscitate should be made jointly by both the physician and the patient; and that if the patient is incapable, close family members should be consulted. As in the Veterans Administration guidelines, there is a specific provision that once the decision is reached, it "shall be written as a formal order by the attending physician" and "the facts and circumstances relevant to this decision shall be recorded by the attending physician in the progress notes. A verbal or telephone order cannot be justified, and should not be done." The full text is annexed as Appendix II.

Despite these guidelines, the president-elect of the Society testified, many physicians still do not feel comfortable writing such an order in the absence of official recognition of the DNR decision as a legitimate medical option. He stated that while the Society does not consider it desirable for government to tell physicians what specific circumstances justify the writing of "do not resuscitate" orders, it would be altogether appropriate for the State to codify the Society's standards as to the decision-making process and, in particular, its strict ban on verbal orders.

The New York State Hospital Association and its Greater New York counterpart have also studied the matter, and unanimously concluded, in the words of its representative, "that it would be far better for everyone concerned if there was a clear set of regulations and guidelines." In 1982, the Board of Governors of the latter group explicitly recognized that it was "simply unfair" for a nurse to be put in the "untenable position" of having to follow an unwritten "no code" order from a physician without any legal guidelines. The Board of Directors accordingly directed the Greater New York Hospital Association's vice-president to write to the State Commissioner of Health to urge regulatory guidance. The letter noted the Medical Society guidelines, stressed the Association's willingness to participate in the rule-making process, and specifically asked the Commissioner to refer the matter to the State Hospital Review and Planning Council. A similar letter was sent by the president of the State Hospital Association. No official response was ever received.

We believe that the public interest urgently warrants a governmental response to these concerns. We believe this response should reflect the reality that "do not resuscitate" orders are regularly given by responsible physicians in circumstances regarded as medically and ethically appropriate and should expressly recognize the prevailing legal view that carrying out such an order does not, in and of itself, violate the criminal or civil law. Responsible physicians should not have to ignore their own best medical judgments or the wishes of their suffering and terminally ill patients out of an unjustified fear of legal consequences. At the same time, the enormous significance of such life-and-death decisions cannot be minimized, and appropriate procedures must be established to assure that they are not made carelessly, unilaterally or anonymously.

We accordingly propose the following recommendations:

RECOMMENDATIONS

The Grand Jury proposes the following legislative, administrative and executive action in the public interest:

1. **WE RECOMMEND** that the State Legislature enact basic standards to regulate the procedures by which physicians decide whether cardiopulmonary resuscitation should be withheld from terminally ill patients, and authorize and direct the Commissioner of Health to promulgate specific regulations to implement and enforce such standards.

This legislation should expressly acknowledge that DNR decisions are unavoidable under the current state of scientific and medical technology, wherein the dying process can be prolonged against the wishes of the patient or his family and beyond the point of any medical or ethical justification.

Further, without necessarily attempting to define the circumstances under which such decisions may be appropriate, the legislation should formally recognize the prevailing legal view that withholding cardiopulmonary resuscitation does not, in and of itself, violate the criminal or civil law.

At the same time, the significance of such DNR decisions, and the demonstrated potential for abuse, require governmental safeguards to assure that these decisions are not made carelessly, unilaterally or anonymously and that they are accurately and permanently documented. Therefore, the legislation should establish, at a minimum, the following basic standards:

1. that such decisions shall be reached jointly by a responsible, licensed physician and the patient or, if the patient is not competent, a family member or other appropriate surrogate;
2. that such decisions shall be made only after the physician has, with a reasonable degree of medical certainty, diagnosed the underlying illness as incurable or untreatable and expected to result in imminent death;
3. that the patient or his surrogate shall be meaningfully apprised of the nature of that illness and its consequences;
4. that if an affirmative decision is reached to withhold cardiopulmonary resuscitation, an order to that effect shall be entered permanently in writing on the medical chart of the patient by a licensed physician who participated in the decision-making process; and
5. that such a decision shall be readily revocable by the physician or the patient or surrogate in the event of a remission or for any other reason.

2. **WE RECOMMEND** that the Commissioner of Health, pursuant to his already existing statutory authority and pending the enactment of the legislation proposed in Recommendation 1 above, promulgate regulations embodying the minimum basic standards enumerated in that recommendation.

These standards can be promulgated, for example, by appropriate amendment of the "Patients' Rights" provisions of the rules and regulations of the Department of Health. 10 NYCRR §405.25. These provisions already set forth the rights of hospital patients to receive complete current information about their diagnosis, treatment and prognosis; to receive information necessary for them to give informed consent to the proposed method of treatment; and to be able to intelligently choose to refuse such consent where it is lawful to do so. These rights can readily be extended to situations where the diagnosis is of an illness which is reasonably certain to result in imminent death; where the proposed course of treatment involves withholding the use of cardiopulmonary resuscitation; and where the patient or his surrogate is called upon to consent or refuse to consent to such a decision. The further requirement of memorializing the DNR decision on the patient's chart is merely designed to assure that the diagnosis has been responsibly arrived at and discussed, and that the patient's right to self-determination has been honored.

3. WE RECOMMEND that the Commissioner of Health further consider whether additional regulatory safeguards should be adopted to assure accountability in this decision-making process, and, if necessary, hold public hearings to assist him in developing such guidelines. Among the additional safeguards which should be considered are:

1. the extent to which the physician with primary accountability for making the decision not to resuscitate should be obligated, before writing the DNR order, to consult with or seek approval from other members of the hospital staff, particularly in cases where more than one physician has treated the patient;
2. the extent to which that order should be subject to periodic review, and by whom; and
3. the extent to which the entire decision-making process and the identity of the other participants should be memorialized in writing.

4. WE RECOMMEND that the Governor stimulate dialogue and coordinate cooperation among the various branches and agencies of government, and between them and the medical profession and the public at large, so that the profound issues surrounding the use of cardiopulmonary resuscitation can be fully discussed, understood and evaluated, and any potential abuses eliminated.

William A. Gallagher
Foreman

Dated: Queens, New York, February 8, 1984

APPENDIX I

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420 August 25, 1983

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics

SUBJ: Guidelines for "Do Not Resuscitate" (DNR) Protocols within the VA

1. As it has in the past, the Veterans Administration remains committed to the principle of supporting and sustaining life, employing new life-saving or life-supporting techniques and therapeutic measures in so doing. However, medical science has made us realize that in some instances the implementation of therapeutic decisions and the application of medical technology may not cure a patient's disease or disability or reverse a patient's course. Some patients who suffer from a terminal illness and are incurable may reach a point where application of additional measures would become not only unwanted but medically unsound. In such cases, the physician is seen as not preventing death, but merely deferring the moment of its occurrence. The significant medical problems then are no longer therapeutic, in the strict sense of curing or treating, but rather ones of choice among degrees of treatment, involving decisions relating to control over the moment and mode of dying. In this connection, the responsible physician faces the problem of determining that continued maximal efforts constitute a reasonable attempt at prolonging life or that the patient's illness has reached such a point that further intensive, or extensive, care is in fact merely postponing the moment of a death which is otherwise imminent.
2. The basic policy of the Veterans Administration continues to be that of providing the highest quality medical care to its patients and beneficiaries, with the objective of sustaining life and practicing in conformity with the highest ethical and medical standards. It is imperative that our Medical Centers and their professional staffs and personnel remain committed to this purpose. However, this commitment should not be so strong as to overwhelm a dying patient's decisions or undermine his/her well-being or his/her right of self-determination.
3. Therefore, it is appropriate that Medical Districts and/or individual Medical Centers consider for adoption protocols for application within that Medical District/Medical Center, to deal with the issues involved when terminally ill patients request that Do Not Resuscitate (DNR) orders be placed in their medical records and/or that they not be resuscitated in the event of a cardiopulmonary arrest. Even though such a protocol may have been adopted, it will continue to be VA policy that CPR will be administered to every patient who sustains a cardiopulmonary arrest, where the medical record does not contain a DNR order that fully complies with the Medical District/Medical Center established policy. However, it is acknowledged that there will be those cases where, in the exercise of sound medical judgment, a licensed physician who knows the patient may appropriately give an instruction not to institute resuscitation at the bedside of a patient who has just experienced an arrest. Such cases would involve patients who were considered terminal, where death was imminent or expected and where resuscitative efforts would most likely have been fruitless. It may be appropriate to communicate these concerns to physicians responsible for the immediate care of the patient, in the absence of the physician who knows the patient.

4. DNR protocols established by VA Medical Districts/individual Medical Centers should contain certain specific items:
    a. An introductory policy statement which sets the tone and delineates specific ethical, legal and medical considerations that may apply;
    b. Specific definitions of such terms or phrases as DNR, resuscitation, terminal illness, and imminent death;
    c. A patient classification scheme, to delineate the class of patients to whom the policy applies;
    d. A description of the patient's (or patient's surrogate's i.e., legally appointed guardian's or representative's) role, with respect to the competent, the incompetent, and the comatose patient, as well the patient hospitalized within a state which has a "Natural Death" or "Death with Dignity" statute;
    e. A description of the family role, where it is relevant;
    f. Requirements for consultation, consensus, or committee involvement;
    g. Requirements for the DNR order itself and who may write it;
    h. Requirements for the accompanying note in the Progress Notes and who may write it;
    i. Limits for time duration of the DNR order and provisions for its review;
    j. Requirements for other or additional medical care, short of resuscitation; and
    k. Requirements for flagging or otherwise highlighting the medical record in such a way as to indicate the entry of a DNR order therein.

5. The following suggestions or recommendations are made with respect to the items listed above:

Definitions:

The terminally ill patient may be defined as one whose underlying condition is considered to be medically incurable or untreatable, in terms of currently available technology, and whose death as a result of the natural history of his/her disease process or medical problem is considered imminent, that is, expected to occur during the course of the current hospitalization. In addition the definition might also apply to those situations where the physician determines that resuscitation would be of no benefit to the patient, because the natural course of the patient's medical condition would result in death imminently and the institution of resuscitative measures, if successful, would only postpone the moment of death for a brief period of time, that is for matter of a few hours or days.

Patient's Role:

Where the patient is competent and alert, and understands the implications of his/her diagnosis and prognosis, the DNR decision should be reached by the patient after discussion with the physician primarily responsible for his/her care. If the patient requests that a DNR order not be written, or instructs that resuscitative measures should be instituted, no DNR order should be written or considered by the treating team.

The patient should be encouraged to discuss the subject with family members before making this decision. However, there are some situations where a competent, alert patient might for one reason or another elect not to inform family members of this decision nor to seek their concurrence. Under the circumstances, patient privacy and confidentiality require that those wishes be respected and honored and that the family not be informed or involved. However, the patient should still be encouraged in this circumstance to involve the family in the decision.

Where the patient is comatose or otherwise incompetent, or incapable of making his/her decision, the decision should be reached after consultation with the patient's surrogate, or in the absence of such an individual, appropriate family member(s) and the physician.

Should the patient's surrogate or family member(s) disagree with the DNR order, no such order will be written. In the event there is question as to the patient's competence, psychiatric consultation should be obtained. Should the responsible physician feel that he/she cannot in good conscience and sound medical judgment comply with the patient's (or patient's surrogate's or family's) wishes regarding resuscitation, that physician should arrange to transfer the patient's care to another physician capable of appropriately and skillfully handling the patient's medical problems, who can so comply.

In situations where an incompetent or comatose patient has no surrogate (legally appointed guardian or representative) or family members, and the treating staff (including the attending physician) feels that a DNR order is appropriate, consultation should be undertaken with the Director/Chief of Staff and the District Counsel for appropriate court order to be obtained, permitting such a DNR order.

States With "Natural Death Laws:"

If the patient resides in a state where statute permits a directive to an attending physician regarding "death with dignity," "right to die," "living will," or similar provisions, prior exercise of that statutory right by a patient may be considered as evidence of that patient's wishes regarding DNR orders, prior to the occurrence of coma or incompetence. However, the absence of such a declaration or directive should not be considered as an indication that the patient would not have wanted a DNR order written unless there is evidence of his/her *specific* wishes in that regard. Where the relevant state statute provides additional requirements to be met regarding diagnosis, prognosis, informing the patient, recordation, witnesses, etc., the requirements of state law should be followed, where they are not inconsistent with the provisions of this circular.

Consultation and Other Physician Involvement:

The individual with specific responsibility for determining the propriety of considering a DNR order in a particular case is the senior attending physician in charge of the patient's care, *not* a house officer. In this context, the ultimate DNR decision should be reached by the patient after discussion with the senior physician in charge of his/her care (staff or attending physician). Medical decisions regarding the patient's diagnosis or prognosis should be reached by a consensus of the medical treatment team. In larger hospitals, this will mean the attending or staff physician, involved house staff, and whatever consultants may be involved in the patient's care (oncologists, cardiologists, etc.). In smaller hospitals, where house staff is not involved with the patient's care and consultants of that level are not readily available, the decision should be reached by the patient's attending or staff physician and the Chief of Service/Chief of Staff. In those situations where there may be some doubt concerning the propriety of a DNR order or the accuracy of the patient's diagnosis or prognosis, a medical ethics or prognosis committee or similar body may convened on an ad hoc basis to help resolve the problem.

Entry of the DNR Order:

After it has been determined that a DNR order is appropriate in a particular case and the foregoing requirements have been met, the order *must be written* into the patient's medical record by the attending physician, rather than a house officer or resident. A verbal or telephone order for DNR is not justifiable as sound medical or legal practice. Once the order has been entered, it is the responsibility of the attending physician to ensure that the order and its meaning are discussed with appropriate members of the hospital staff, particularly the nursing staff, so that all involved professionals understand the order and its implications.

Accompanying Entry In The Progress Notes:

At the time a DNR order is written, a companion entry should be made in the progress notes, which includes at a minimum the following information: the diagnosis, the prognosis, the patient's wishes (when known), the wishes of patient's surrogate or family member(s), where relevant, and the consensual decisions and recommendations of the treating team and consultants, with documentation of their names. In addition, there should be some reference concerning the patient's competency, where the decision was based on his/her concurrence, and applicable documentation of any "informed consent."

Where the competent patient has requested that his/her family not be involved in or informed of his/her decision, as noted above, the patient's decision and request for confidentiality should be documented in the medical record by a disinterested third party, not a member of the treatment team, e.g., a patient ombudsman or representative, a representative of Medical Administration Service, etc.

Review of the Order:

The protocol should specify the process of review for such a DNR order, and how often review should be carried out. Obviously, any time there is a significant change in the patient's medical condition, the order would automatically become void. As in any medical situation, a DNR order may be rescinded at any time by the physician at the specific request of the patient, patient's surrogate, or family member.

Related Medical Care:

It is important that all involved understand the fact that a DNR order is compatible with maximal therapeutic efforts short of resuscitation, and that the patient is entitled to receive vigorous support in all other therapeutic modalities, even though a DNR order may have been entered. It may be appropriate then, in these circumstances, to write onto the order sheet those medical efforts which will be maintained to relieve suffering and assure patient comfort, including basic nursing care (body cleanliness, mouth care, positioning); adequate analgesia; suction; intake for comfort, including hydration; and oxygen for comfort. Merely because a DNR order has been entered into a patient's record does not mean that there is justification for ignoring the patient or providing him/her less than humanistic care and concern for his/her welfare and comfort.

Conclusion:

DNR protocols can be developed to effectively deal with the trauma and suffering that frequently accompany the circumstances in which such orders are written. These protocols must give fair consideration to the patient's medical needs, the social and psychological needs of the patient's family, the legal rights and responsibilities of physician and patient, the professional needs of hospital administration and staff, and applicable state law. With the assistance of all involved, and District Counsels, sound protocols can be developed and implemented. Obviously, no patient shall be considered for a DNR order in anticipation of possible problems such as might occur as the result of unforeseen difficulties during hospitalization or as a result of surgery or in any case where the patient is not terminally ill. Under no circumstances should DNR orders be written where they are in compliance only with a request for "assisted suicide" or voluntary euthanasia. "Do Not Resuscitate" does not mean that the medical staff will take any affirmative steps to "hasten the patient on his/her way." All parties including all levels of providers should try to provide and improve acceptable therapeutic options available to the dying patient.

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

APPENDIX II

Guidelines for Hospitals and Physicians on "Do Not Resuscitate," Medical Society of the State of New York

The following are intended only to be guidelines for physicians and hospitals. Hospital medical staffs and governing bodies are encouraged to develop policies consistent with their respective by-laws and rules and regulations.

Definition

DNR (Do Not Resuscitate) means that, in the event of a cardiac or respiratory arrest, cardiopulmonary resuscitative measures will not be initiated or carried out.

Background

1. An appropriate knowledge of the serious nature of the patient's medical condition is necessary.
2. The attending physician should determine the appropriateness of a DNR order for any given patient.
3. DNR orders are compatible with maximal therapeutic care. A patient may receive vigorous support in all other therapeutic modalities and yet a DNR order may be justified.
4. When a patient is capable of making his own judgments, the DNR decision should be reached consensually by the patient and physician. When the patient is not capable of making his own decisions, the decision should be reached after consultation between the appropriate family member(s) and the physicians. If a patient disagrees, or, in the case of a patient incapable of making an appropriate decision, the family member(s) disagree a DNR order should not be written.

Implementation

1. Once the DNR decision has been made, this directive shall be written as a formal order by the attending physician. A verbal or telephone order for DNR cannot be justified as a sound medical or legal practice.
2. It is the responsibility of the attending physician to insure that this order and its meaning are discussed with appropriate members of the hospital staff.
3. The facts and considerations relevant to this decision shall be recorded by the attending physician in the progress notes.
4. The DNR order shall be subject to review at any time by all concerned parties on a regular basis and may be rescinded at any time.

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Drunken Injured Drivers: Are They "Getting Away with Murder"?

ALLAN A. BRANDT, M.D., JAY WALSHON, M.D. AND JOHN J. KELLY, J.D.

"In Connecticut as in other states throughout the country, drunk drivers kill and maim themselves, their passengers, the occupants of other vehicles and pedestrians. Victims as well as drivers are being devastated physically, emotionally and financially."[1]

Deaths and injuries due to driving while intoxicated (DWI) are a major Emergency Medical Services and Public Health problem of our age, and largely preventable. In fact, during the last five years, DWI has become a focus of *national revulsion* and a compelling concern for remedial action because it has resulted in incalculable suffering to drivers, innocent victims and families at a yearly cost to our society of 17,847 highway deaths, 750,000 injuries and 24 billion dollars.[1-2]

Yet the culprit of the carnage on our highways, the drunken injured driver, is seldom cited for DWI and even more rarely convicted.[3] At the core of the problem is the precarious balance between the individual drunk driver's rights versus those of society. And too, the inability to obtain objective evidence, readily available, of guilt or innocence and introduce it into court proceedings. Powerful forces, some quite bizarre, protect the drunken injured driver from punishment.

Almost daily our newspapers are filled with increasing reaction to the drunk driver. Police blockades to screen out drivers who may be drinking alcohol; setting of age 21 as lower age to purchase alcohol; ordinances in some cities that abolish "happy hours"; laws in many states, Connecticut among them, that set test limits for alcohol intoxication and explicit punishment, including loss of license, fines and even jail for offenders; and court decisions that fix blame for death on the server of alcohol to the intoxicated highway killer. And too, the springing up of multiple grass roots victim reaction groups such as "Mothers Against Drunk Driving" (MADD), "Students Against Driving Drunk" (SADD) and "Remove Intoxicated Drivers" (RID), all concerned segments of the public deeply dedicated to the elimination of the drunk driver.

At the root of these reactions is the frustration, dispair and anger about the personal loss of loved ones or painful costly disability. And more, resentment about a judicial system that permits the minimal or complete lack of punishment of the drunken driver who often walks away unharmed from an accident which devastated the lives of others.

Emergency Physicians have long been aware that drunken injured drivers are seldom charged with DWI or convicted despite the reek of alcohol on the breath, evidence of blatant intoxication clinically and high blood alcohol concentrations (BACs). Yet these drivers are the cause of a forceful national mobilization against drunk driving. They are the targets of the DWI laws and are its greatest offenders. The question is: "Why do they escape punishment?

The goals of this study were: (1) to provide data that would show the frequency of alcohol intoxication in those injured drivers brought to the hospital by ambulance and suspected of DWI; (2) to determine how often such drivers were cited and convicted for DWI; (3) to understand factors which prevent such citations; (4) to recommend changes in legislation; and (5) to sensitize the public with such information for use in the national campaign against DWI.

Methods

During the ten-week period extending from November 28, 1983 to February 27, 1984, thirty patients were selected for study because they fulfilled three criteria: They were drivers of motor vehicles involved in an accident, brought to the hospital by ambulance and were suspected of DWI because of alcohol on the breath. All such patients had blood alcohol levels drawn as quickly as the immediate priorities of medical care were addressed and regardless of whether the patient was admitted or discharged. Data were obtained about the date, name, age, sex, time of arrival, nature of injuries and medical disposi-

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ALLAN A. BRANDT, M.D., JAY WALSHON, M.D., both of the Department of Emergency Medicine, Milford Hospital, Milford, CT. JOHN J. KELLY, J.D., State's Attorney, Judicial District of Ansonia-Milford, Milford Courthouse, Milford, CT.

tion of the patient. The type of motor vehicle accident was investigated and whether or not there were passengers and their dispositions. Efforts were made to determine whether the patient was cited for an infraction of the law and the nature of that citation. Through later follow-up of court actions it was learned whether convictions were obtained.

Results

Twenty-nine of thirty patients (96.7%) with alcohol on the breath had blood alcohol concentrations stipulated by law as showing alcohol impairment (BAC 75-99 mg%) or intoxication (BAC above 100 mg%) (Table 1). Twenty of the twenty-nine drivers had more than two-thirds the legal intoxication limit.

Table 1

BLOOD ALCOHOL LEVELS OF 30 INJURED DRIVERS SUSPECTED OF DWI

mg%	*# Pts*	
25	1	Not intoxicated (3.3%)
75	1	Impaired or Intoxicated (96.7%)
100-199	8	
200-299	15	
300-399	4	
400 +	1	

All but one of the 30 DWI suspect injured drivers had blood alcohol levels above 100 mg% 20 (68.9%) were over 200 mg%.

Of the 29 injured drivers proven to be intoxicated by BAC, 22 (75.8%) were male and 5 (17.2%) were under 21 years of age. Twenty-five operators (86.2%) were alone in the car at the time of the accident. Four drivers were admitted and 25 (86.2%) were discharged. There were eight passengers in all cars of which three were admitted, four were discharged and one was dead on arrival. The three passenger admissions and one death were the result of a single accident in which the driver, also admitted, had a BAC of 180 mg%. Most accidents 22 (73.3%) occurred on weekends and 12 (40%) occurred in the period from 12 A.M. to 5 A.M.

Table 2

POLICE ACTION ON 29 DRUNKEN INJURED DRIVERS

Citation	*#Drivers*	*Conviction*
DWI	2 (6.9%)	1 (3.4%)
"Drinking While Driving" Written Warning	8 (27.6%)	
"Rules of the Road" Violation	9 (31%)	9 (31%)
No Charge	10 (34.4%)	

Despite blood levels above legal levels of intoxication in all above drivers 10 (34.4%) received no charge only 2 (6.9%) were charged with DWI; and only 1 (3.4%) DWI conviction was obtained.

Despite strong clinical suspicions that 29 of the 30 drivers were intoxicated, confirmed by BACs as above the legal limit, only two (6.9%) were charged with DWI and only one (3.4%) conviction was obtained (Table 2). Eight drivers (27.6%) were given written warnings for "driving while drinking." Such warnings are recorded on an individual's license and cost a point against renewal and obtaining insurance. However, such citations do not carry the harsher penalties of DWI. Nine drivers (31%) received summonses for "violations of the rules of the road" and all were convicted. Those convictions are far less punitive than those for DWI. Ten operators (34.4%) were not charged with any violations.

Of 14 head injured drivers, almost half the intoxicated operators, only 1 (7.1%) was cited or convicted for DWI (Table 3).

Table 3

BLOOD ALCOHOL LEVELS OF 14 HEAD-INJURED DRIVERS

mg%	*#Drivers*
76-99	1
100-199	4
200-299	7
300-399	2

Despite the fact that head injuries were present in almost half of the drunken injured drivers, many reeking with alcohol, only 1 (7.1%) was cited for DWI.

Discussion

At a time when prevention of trauma in general has become a national priority, alcohol-related highway injuries and deaths are being viewed with deep concern by Emergency Medical Services and Public Health organizations, state legislative bodies and courts, and aggrieved victims of drunken drivers.

In 1983 there were 42,584 fatalities as a result of MVA's and 42% of those fatalities were associated with alcohol intoxication.[2] Thirty per cent of the drivers causing fatalities were 16 to 24 years old of whom 38% were intoxicated. Fifty-one per cent of the fatalities in the latter age group were the young drivers themselves. More than 750,000 people are injured each year due to drunk driving and in the last decade 11 million American families have had a member killed or injured by a drunken driver. Deaths and injuries in drunk driving crashes account for an expenditure of $24 billion dollars each year.[1] Yet the drunken driver in Connecticut may get away with little more than having to attend rehabilitation meetings despite the fact that serious injury has resulted from a motor vehicle driven by him.

Indeed, Maull showed that in a study of 56 injured drivers admitted to the hospital, all with BACs in excess of 150 mg%, not one was cited for DWI.[3]

The drunken injured driver is strongly protected by the 4th and 5th Constitutional Amendments, by court decisions which require behavioral confirmation of alcohol intoxication (not just alcohol on the breath), by state legislation which goes beyond rights protected by the United States Constitution, by police attitudes and by weak punishment provisions in the state law.

The gathering of essential evidence of alcohol intoxication, the blood, breath or urine sample of a suspect driver, and its introduction into evidence have been difficult. This difficulty has been caused by legislation, based in part on the provisions of the 4th and 5th Constitutional Amendments relating to illegal search and seizure and to self-incrimination, which require police to obtain his written consent before obtaining an alcohol test. Many state legislatures have gone beyond requirements established by decisions of the Supreme Court. In Connecticut, for example, the prosecution in a DWI trial cannot introduce evidence that the defendant refused to take an alcohol test, yet in South Dakota v. Neville,[4] the US Supreme Court ruled that admitting into evidence a defendant's refusal to take an alcohol test did not violate his 5th Amendment right against self-incrimination.

Because the side-effects of head injury and alcohol intoxication are so similar, the police and prosecuters know that such citations and prosecutions are usually a waste of time. Paradoxically, injury actually confers legal immunity on the DWI driver instead of contributing to the evidence that such injuries are more common in DWI. Moreover, there is a misunderstanding of the term "head injury" since the police have been known to avoid DWI citation in the presence of minor injuries such as a lip laceration.

Another problem is the reluctance of some police officers to make DWI arrests. Some officers fear being sued for false arrest. Others believing at times that the DWI law is too harsh have empathy for the young driver, particularly as it may cause loss of license to drive and perhaps loss of a job.

Theoretically, in Connecticut, a person convicted of DWI faces a substantial penalty. First offenders face a jail term of six months, a fine of not less than five hundred dollars nor more than one thousand dollars and suspension of his drivers license for one year (S14-227a). But a giant loophole exists. Under S54-56g, a first offender is eligible to enter a "pretrial alcohol education system" rather than stand trial. Under this law a person is not prosecuted for DWI but is referred to the probation department in order to attend a minimum of eight meetings or "counseling sessions" on alcohol education and treatment. A fee of $250.00 is imposed on those people accepted into this program. If the person attends the meetings and is not arrested again for DWI for a period of one year, the DWI charge is dismissed!

Unlike another Connecticut statute entitled "accelerated rehabilitation," which is a similar diversion program for people accused of "non-serious" crimes, S54-56g does not provide that where the DWI arrest involved either injury to another person or another person's property, that person has no right to be notified or heard when the person arrested for DWI seeks to enter the pretrial alcohol program. This obviously results in nothing more than a "slap on the wrist" for the first offender DWI driver.

DWI is obviously a complex problem and includes chronic alcoholics and chronic offenders. Maull[3] found that 16% of the drivers studied had one or more previous convictions for DWI; 33% had previous convictions for reckless driving; and 36% had previous license suspension and a crash.

The chronic alcoholic is and will continue to be a problem but certain weaknesses in law enforcement and the law should be addressed to signal the public, drivers and victims alike that DWI is to be dealt with firmly. Police should be allowed to stop and briefly detain people they reasonably suspect of DWI. During this detention police should have the authority to administer an alcohol test.[5] The odor of alcohol on the breath should be sufficient reason to suspect that a person is DWI and to require an alcohol test, *whether or not that person is injured;* it is reasonable to believe that "where there is smoke there may well be fire." State law should be changed to permit introduction at DWI trials of evidence that the defendant refused an alcohol test. State law also should be changed to require that a person arrested for DWI be prosecuted for that offense and upon conviction be subjected to a minimum $1,000 fine and loss of license. After conviction, alcohol education and treatment should be compulsory.

The victims of DWI are right, the current judicial system is far too lenient on the drunk driver who gets away with minor punishment for major negligent deeds.

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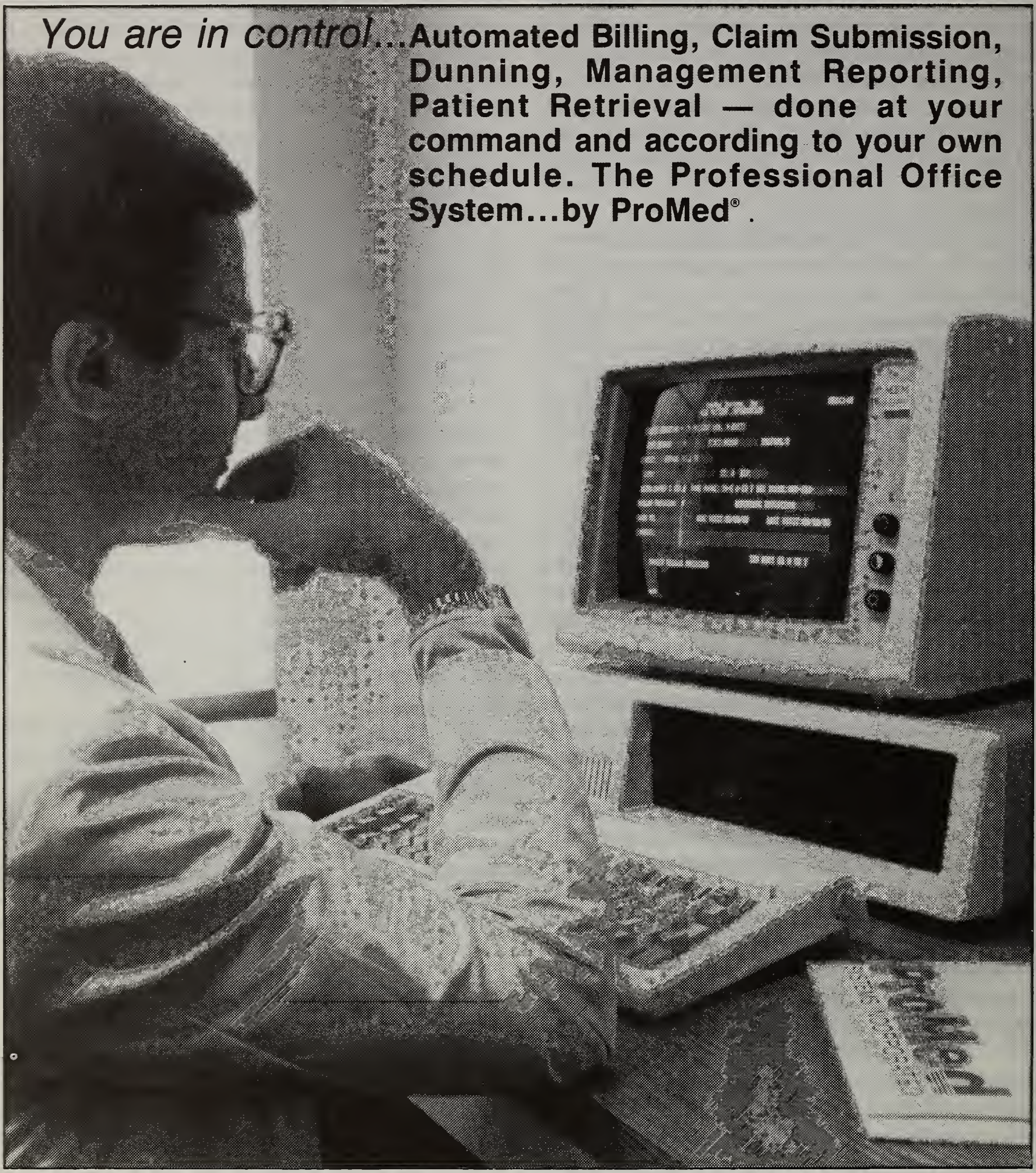

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The Origins of Anesthesia

Part V

SHERWIN B. NULAND, M.D.

THE INTRODUCTION OF ETHER ANESTHESIA

The prologue is complete. Everything that has been described to this point is background and color for the ultimate dramatic act in the story of anesthesia, the successful operation by John Collins Warren upon a patient etherized by William Morton, on October 16, 1846.

It is difficult to make any sense of the emotional cacaphony that came in the aftermath of that event without some concept of the personality of its leading player. What emerges from the various descriptions by those who knew William Morton is perhaps best illustrated by a 20th century term: he was a young man in a hurry. Ambitious in both the best and least-best senses of that word, he was hard-working, quick to grasp an opportunity, and very much aware of the financial rewards that can come with discovery. Whatever benefit he hoped to reap for mankind, he seems to have been driven more by motives characteristic of a corporate executive than of a selfless scientist. In fact, he was not a scientist in any sense—he was, pure and simple, an inventor looking for a bonanza.

Although practicing dentistry in Boston, Morton had never completed the studies he had undertaken in 1840 at the Baltimore College of Dental Surgery. But he did have every desire to improve his knowledge of technical matters and accordingly attended two courses of lectures at the Massachusetts Medical College, during which he made the acquaintance of several members of the staff at the Massachusetts General Hospital. He studied chemistry privately with Charles T. Jackson, in whose house he was a boarder for a brief period. Jackson, although a highly respected geologist, also directed a laboratory for research in analytical chemistry.

At the time we pick up the thread of Morton's life he had established himself in dental practice in Boston, after an unsuccessful partnership with Horace Wells in Hartford during 1842-43. It was Morton who had been instrumental in arranging Wells' unfortunate nitrous oxide demonstration with John Collins Warren in February, 1845, and he had been not only a witness to its failure but also to some of his erstwhile associate's experiments. Whether, as Wells later claimed, he was also experimenting with sulfuric ether in Morton's presence is uncertain.

Morton, in 1844, was actively searching for some method of relieving the pain of dental extractions. Finding it had become a very practical economic matter with him, because his technique of fitting dentures required that all broken tooth stumps be removed from the jaws, a practice so uncommon among his colleagues that he was losing patients to other dentists because of it. In connection with the financial consequences of Morton's painful denture technique, some further insight into his personality is provided by a statement made several years later by an involved attorney, the forthright and by then famous Richard Henry Dana, Jr.: "Thus, Dr. Morton had a direct pecuniary motive, bearing almost daily upon him, to alleviate or annihilate pain under his operations." There seems to have been a certain urgency about the entire undertaking, not only to accomplish it quickly, but to be the sole beneficiary of whatever financial rewards might come.

It is known that Charles Jackson had, in that same year, told Morton of the effect that ether had upon frolicking students, and it is also known that Jackson had suggested to Morton that he apply ether directly on the soft tissue around any tooth he wished to extract, to numb the local area. Based on that advice the young dentist had first used this method in July, 1844, and had begun to ponder the possibility of using the liquid or its vapors to induce some more general decrease in systemic sensation. He knew from his reading of Jonathan Pereira's 1839 *Elements of Materia Medica* that inhaling the vapors of sulfuric ether would induce obtundation similar to that caused by nitrous oxide, and he began, very much in secret, to seek out a safe method of using it. Much of the summer of 1846 was spent in experiments with goldfish, caterpillars, insects, worms, and even a spaniel puppy. He finally tried the vapours on two of his young dental apprentices, but could not convince himself that the results were predictable or satisfactory. All of his work was done in the greatest

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SHERWIN B. NULAND, M.D., Associate Clinical Professor of Surgery, Yale University School of Medicine. Dr. Nuland is Literary Editor of *Connecticut Medicine*. This is Chapter V of Dr. Nuland's book *The Origins of Anesthesia*.

secrecy, but the secrecy itself impeded its progress by preventing Morton from asking advice from appropriate sources, for fear that his idea would fall into the hands of another. But in spite of a certain daring (or, as some thought, a recklessness) Morton never did have a lot of faith in his own scientific knowledge, and eventually consulted his erstwhile chemistry mentor, Jackson. The older man recommended that Morton discard the use of the commercial product, and restrict himself to pure sulfuric ether. He probably also encouraged him to try the inhalation technique on a patient named Eben Frost, who presented himself at Morton's office on the evening of September 30, 1846. The extraction of a tooth was accomplished on the sleeping, pain-free Frost, and Morton immediately made plans to go forward with a public demonstration. But as quick as he was in his desire to show the world that he had discovered pain-free surgery, the pragmatic Morton first took the precaution of consulting a patent commissioner.

He took one other precaution as well, even before seeking advice on a patent—he contacted a newspaper. Although Morton claimed that he was not the source of it, it is hard to believe that anyone else was the anonymous informant for the following notice which appeared in the *Boston Daily Journal* on the next day, October 1, 1846:

> *Last evening, as we were informed by a gentleman who witnessed the operation, an ulcerated tooth was extracted from the mouth of an individual, without giving the slightest pain. He was put into a kind of sleep, by inhaling a preparation, the effects of which lasted for about three quarters of a minute, just long enough to extract the tooth.*

Morton's next move was to visit John Collins Warren, a step which, in light of his association with the nitrous oxide misadventure, furnishes an example of his considerable self-confidence or considerable foolhardiness, or perhaps a good measure of each. It certainly flew in the face of scientific restraint, in view of the fact that the 27 year old dentist's experience with ether was minimal, his knowledge of its hazards was nil, and he had not yet even bothered to do anything about perfecting an apparatus by which the gas could be administered to a human subject, the operation on Frost having been done with an ether-soaked handkerchief. Warren had every reason to reject Morton's suggestion that ether be used for a surgical operation.

But here the character of John Collins Warren comes into play. An austere, highly skilled physician with considerable drive, he had studied his operative techniques with the likes of Sir Astley Cooper and Baron Guillaume Dupuytren, the greatest European surgeons of their day. Although known for his prudence and good judgment, he was also known for his willingness to try new methods, having been a pioneer in certain orthopedic procedures, and the first surgeon in America to operate for strangulated hernia. He was Harvard's second Professor of Surgery, having succeeded his own father to that position in 1815. As one of the founders of the Massachusetts General Hospital and of the American Medical Association he was, at the time that Morton approached him, one of the young country's most revered senior physicians.

In 1846, Warren was 68 years old, and within one year of relinquishing his professorship. His flint-faced, grizzled appearance belied the fact that in a lifetime of surgery he had never been able to inure himself to the horrors of the operating theater—even his devout Christian faith did not shield his conscience against the agonies to which he exposed the very bodies he was trying to heal. Perhaps it was his ineluctable destiny to be the medium by whom, in the words of his friend Oliver Wendell Holmes, "the fierce extremity of suffering has been steeped in the waters of forgetfulness, and the deepest furrow on the knotted brow of agony has been smoothed forever." He accepted Morton's proposition.

As much as Morton had wanted to proceed with all possible speed, he must have been taken aback by the quickness of Warren's reply, for he had not yet constructed an apparatus that could be utilized. With only 48 hours notice, a short letter sent him at Warren's request by C.F. Haywood, House Surgeon to the Massachusetts General Hospital, invited him to the hospital "to administer to a patient who is then to be operated upon, the preparation which you have invented to diminish the sensibility to pain." So secretive had Morton been that even the operating surgeon himself did not know of what "the preparation" consisted.

Morton worked feverishly with an instrument maker to fashion a functional device, which was completed so close to the last instant that he arrived at the operating theater 15 minutes late on the appointed morning, just as Warren, despairing of his appearance, was poised to begin the operation without him. The seats of the amphitheater were filled with staff and students, many of them prepared to enjoy the humiliation of yet another dentist with a humbug remedy for surgical pain. The patient was a thin, tuberculous young man, Gilbert Abbot, with a vascular tumor at the angle of his left jaw. After saying a few encouraging words to the proposed subject, Morton positioned the mouthpiece of the apparatus and told Abbot to breathe.

Within a few minutes Gilbert Abbot was asleep. Morton looked over toward Warren and announced, "Sir your patient is ready." The procedure began.

The wound was sutured, and Abbot began to awaken. In answer to Morton's question, he stated that he had felt no pain. John Collins Warren looked up at what had been, just moments before, a skeptical, even cynical, audience, its members now hushed into an awesome reverential silence that must have come with the certain knowledge that they had been present at one of medicine's rites of passage. He looked up at them, still thunderstruck at what had just been accomplished, and quietly introduced the era of pain-free surgery with an eloquently simple pronouncement: "Gentlemen, this is no humbug."

When he had some time to collect his thoughts and to ponder over the realization of his lifelong dream of surgery without pain, he wrote, in 1848:

> *A new era has opened on the operating surgeon. His visitations on the most delicate parts are performed, not only without the agonizing screams he has been accustomed to hear, but sometimes in a state of perfect insensibility, and, occasionally, even with an expression of pleasure on the part of the patient.*
>
> *Who could have imagined that drawing a knife over the delicate skin of the face, might produce a sensation of unmixed delight? That the turning and twisting of instruments in the most sensitive bladder, might be accompanied by a delightful dream? That the contorting of anchylosed joints should coexist with a celestial vision?*
>
> *If Ambroise Paré, and Louis, and Dessault, and Cheselden, and Hunter, and Cooper, could see what our eyes daily witness, how they would long to come among us, and perform their exploits once more.*
>
> *And with what fresh vigor does the living surgeon, who is ready to resign his scalpel, grasp it, and wish again to go through his career under the new auspices.*
>
> *As philanthropists we may well rejoice that we have had an agency, however slight, in conferring upon poor suffering humanity so precious a gift.*
>
> *Unrestrained and free as God's own sunshine, it has gone forth to cheer and gladden the earth; it will awaken the gratitude of the present, and all coming generations. The student, who from distant lands or in distant ages, may visit this spot, will view it with increased interest, as he remembers that here was first demonstrated one of the most glorious truths of science.*

Students, from distant lands and in distant ages, have indeed made pilgrimages to that spot, now called the Ether Dome of the Massachusetts General Hospital.

The following day another patient was operated upon, this time by Dr. George Hayward. The patient remained unconscious throughout the entire brief procedure. The results of the previous day had been confirmed, and there was no reason to delay further clinical trial. On the same day, the people of Massachusetts heard of the great event by reading the first printed reference to it in the *Boston Daily Journal*, with a similar note appearing in the *Boston Post.* This time it was not Morton who went to the newspapers, but one of the surgeons of the hospital, Henry Jacob Bigelow.

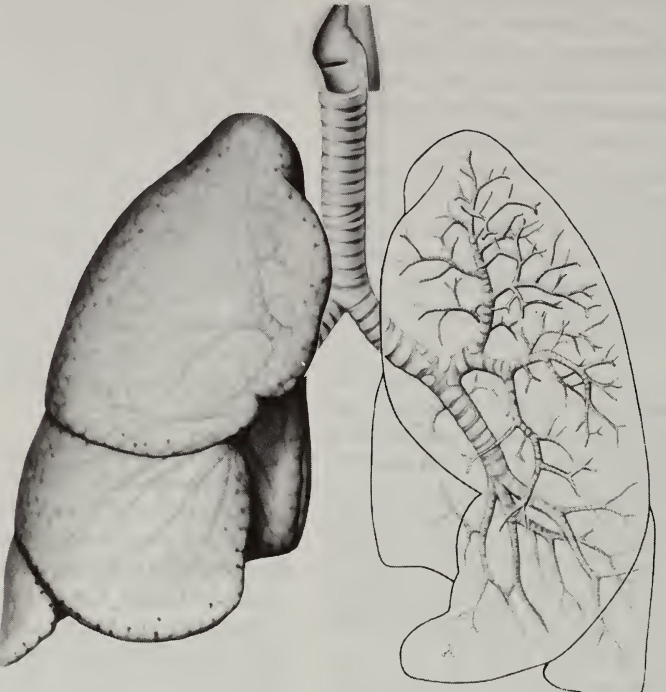
> *Successful operation. Yesterday, Dr. Morton, Dentist, No. 19 Tremont Row, at the invitation of Dr. Haywood, visited the McLean [misprint for Massachusetts General] Hospital, and administered his preparation to produce sleep, to a person about to undergo the operation of the extraction of a tumor from the neck. We learn from a gentlemen who conversed with one of our oldest and most respected physicians who witnessed the operation, that the success of Dr. Morton's experiment was complete. The patient sitting in a chair, with every thing made ready by Dr. Warren, who extracted the tumor, inhaled the preparation for a very brief space of time, when he fell into a quick slumber, and the surgeon proceeded to extract the tumor. The patient did not manifest the slightest symptoms of suffering, and no muscular action whatever. He appeared to be totally insensible to what was going on, til very near the close of the operation, which was quite protracted, when he drew a long sigh. It is quite as much for the interest of the surgeon as for the patient, that the preparation should be administered, for while it renders the latter insensible to the pain attending severe surgical operations, it affords the former the means of doing his work, freed from all interruptions on the part of the patient, and gives him facilities for performing operations in the most expeditious manner.*

Morton had not yet disclosed the nature of his invention. Optimistically afloat on a wave of acclaim from the hospital authorities, he continued to focus his thoughts on patents, profits, and covering a world-wide market. His biographer, Nathan P. Rice, later estimated in his *Trials of a Public Benefactor* (1859) that by selling rights to exclusive use of the gas in America alone, Morton's share would have been more than $350,000 over the 14 year period of a patent. The letter written to Wells on October 19 describes his planned approach, and provides a good example of the young entrepreneur's tendency to pad facts and distort events.

But two problems had arisen. The first was Morton's increasing inability to keep the nature of his gas a secret. His addition of aromatic compounds to the mixture could not disguise its characteristic odor from physicians, and even his denial that ether was the active ingredient would only delay discovery for a short time. He had to act quickly to establish his claim on any strong legal grounds.

The other problem was the intervention at this moment of Charles T. Jackson. On October 23, Jackson came to visit Morton, and with that confrontation began a conflict that would become so acrimonious and finally so vicious that it did not end even long after both participants had been destroyed by its unremittent fury. Simply stated, Jackson wanted a piece of the action; the patent commissioner R.H. Eddy, who, as it turned out, was one of the highly-regarded Jackson's many admirers, had concluded that it was probable that a patent on ether could be obtained, and he was now urging Morton to give his colleague a percentage of the profits that might be made. The two came to an agreement. On November 12, 1846, Letter Patent No. 4848 was issued to both Morton and Jackson, with Jackson having agreed to assign his rights in the patent in return for a ten percent share of the American profits; a similar patent was later taken out to cover foreign sales. The conflict was, for the moment, stilled.

Consider the causative organisms...



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Brief Summary Consult the package literature for prescribing information

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out

Precautions: *General Precautions* – If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy – Pregnancy Category B – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients)

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information

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Effects of Competition in Medicine: Practice Characteristics of Physicians in Proprietary and Nonproprietary Hospitals

AMA COUNCIL ON MEDICAL SERVICE

Council on Medical Service Report C (I-83) indicated the Council's intention to study further the increased involvement of profit-making organizations in the delivery of health care. Since that time, further study by the Council of the impact of the increasing role of for-profit organizations in the health sector has focused on physician practice attributes in proprietary and nonproprietary hospitals. The purpose of the present report is to highlight findings of that study.

As noted in the Council's Report C on the effects of competition, there has been substantial growth in the role of investor-owned "for-profit" organizations in the health care sector. One researcher estimates that publicly held corporations derived $118 billion in revenue out of the total of $322 billion spent on health care in the United States in 1982.[1]

An important manifestation of the growing role of for-profit organizations in the health sector is the increasing number of hospitals and other health facilities that are owned or managed by these companies. In 1983, for-profit businesses owned about 15 percent of all the acute-care general hospitals in the country, more than 60 percent of all nongovernment psychiatric hospitals, nearly 75 percent of all nursing homes, and about 40 percent of all dialysis units.[2] Many of these facilities have become integrated into nationwide chains. Some analysts have predicted that by 1990 for-profit organizations will control 20 percent of the hospital market.[3]

Recently, there has been a heightened interest by physicians and the public in the consequences of the growing role of for-profit enterprises in the health care sector. However, evidence supporting or refuting many of the claims regarding benefits and drawbacks of for-profit organizations is still inconclusive. For example, in the Council's Report C (I-83) evidence was discussed that raised considerable uncertainty as to the cost-effectiveness of for-profit hospitals compared to not-for-profit hospitals. A recent review of the literature on multihospital systems by Ermann and Gabel indicates that while existing evidence is fairly conclusive in showing that for-profit hospital systems have greater access to capital markets than not-for-profit systems, evidence relating to the accessibility and quality of care in for-profit and not-for-profit hospital systems must be regarded as inconclusive since studies on these subjects have all suffered from serious methodological flaws.[4]

The extent of physician involvement with proprietary hospitals, the subject of the present report, is indicated by results from the first quarter 1984 Socioeconomic Monitoring System (SMS) survey. These results indicate that approximately one out of every eight physicians (12.6%) with hospital admitting privileges admit their patients primarily to a proprietary hospital. However, the involvement of physicians with proprietary and nonproprietary hospitals is not mutually exclusive since many physicians have staff memberships at more than one hospital. Physicians whose primary hospital is nonproprietary have privileges at an average of 2.2 hospitals, while physicians who primarily admit their patients to proprietary hospitals have privileges at 2.8 hospitals. Taking multiple staff memberships into account, nearly one out of every four physicians with hospital privileges has some contact with the proprietary hospital sector.

Specific information examined in the remainder of this report includes:

- differences in the practice characteristics of physicians in proprietary and nonproprietary hospitals;
- medical staffing patterns in proprietary and nonproprietary hospitals; and
- the development and/or implementation of programs designed to monitor and influence physician behavior in the hospital by proprietary and nonproprietary hospitals.

EDITOR'S NOTE: The following is a report of the AMA Council on Medical Service to the House of Delegates at its Interim Meeting in December, 1984.

With respect to these specific characteristics, it appears that physician practice attributes within the two types of hospitals are similar. However, it is cautioned that there may be differences in characteristics other than those examined. Furthermore, the extent of similarity may decrease if proprietary and nonproprietary hospitals adopt different responses to the movement toward prospective pricing systems.

Practice Characteristics of Physicians in Proprietary and Nonproprietary Hospitals

Table 1 presents a comparison of selected practice characteristics of physicians who primarily admit their patients at proprietary and nonproprietary hospitals, respectively based on information from respondents in the first quarter 1984 Socioeconomic Monitoring System survey. Among physicians in the survey, the average differences in hours worked, patient visits, and hospital utilization between those who admit most of their patients to proprietary and nonproprietary hospitals were relatively small. Furthermore, there is no statistically significant difference between physicians in the two types of hospitals with respect to these characteristics.

Table 1

AVERAGE PHYSICIANS' HOURS WORKED, PATIENT VISITS AND HOSPITAL UTILIZATION BY TYPE OF HOSPITAL AT WHICH PHYSICIANS ADMIT MOST OF THEIR PATIENTS, 1983*

	Proprietary Hospitals	*Nonproprietary Hospitals*
Hours Worked Per Week		
Total	54.0	56.0
Office	25.4	24.5
Hospital	9.2	9.7
Visits Per Week		
Office Visits	80.0	82.8
Visits on Hospital Rounds	36.1	39.2
*Hospital Utilization***		
Patients Discharged Per Week	4.1	4.9
Length of Stay (Days)	6.2	5.7

*Sample includes only physicians with hospital admitting privileges. No differences between proprietary and nonproprietary hospitals shown in the table are statistically significant.

**Data relate to utilization only of the hospital at which physicians admit most of their patients.

SOURCE: American Medical Association, First Quarter 1984 Socioeconomic Monitoring System Survey.

Medical Staffing Patterns in Proprietary and Nonproprietary Hospitals

An important question in the examination of proprietary and nonproprietary hospitals is whether medical staffing patterns in proprietary hospitals are different from medical staffing patterns in nonproprietary hospitals. If medical staffs are widely varied, it may afford one type of hospital a competitive advantage over the other and permit it to gain a larger market share. Information from the American Hospital Association on the medical staffing patterns of proprietary and nonproprietary hospitals is shown in Table 2.

Table 2

MEDICAL STAFF PER 100 BEDS IN PROPRIETARY AND NONPROPRIETARY HOSPITALS*

	Number of Staff		*Percent of Total Staff*	
	Proprietary	*Nonproprietary*	*Proprietary*	*Nonproprietary*
*Total Staff***	49.8	37.3	100.0	100.0
General/Family Practice	8.7	7.9	17.4	21.2
Medical Specialties	14.1	10.6	28.3	28.4
Surgical Specialties	17.1	11.6	34.3	31.0
Hospital Specialties***	4.9	4.1	9.8	11.0
Board-Certified Staff	28.8	24.6	57.8	65.9
General/Family Practice	3.2	3.2	6.4	8.5
Medical Specialties	8.4	7.2	16.9	28.4
Surgical Specialties	10.9	8.5	21.9	22.8
Hospital Specialties***	3.4	3.2	9.8	11.0

*Includes both active and associate medical staff members.

**Includes other specialties not reported separately.

***Hospital specialists include anesthesiologists, radiologists, and pathologists.

SOURCE: American Hospital Association 1982 Annual Survey

On average, proprietary hospitals have more total medical staff, including both active and associate members,* than nonproprietary hospitals. In 1982, proprietary hospitals had an average of 49.8 medical staff per 100 beds compared to 37.3 medical staff per 100 beds in nonproprietary hospitals. However, the share of medical staffs accounted for by each of the major specialty groups shown in Table 2 is similar. Proprietary hospitals also have a greater *number* of board certified staff than nonproprietary hospitals, but the percent of the total staff that is board certified is higher in nonproprietary hospitals, both overall and for each major specialty group.

Influences of Hospital Ownership on Physician Practice Behavior

There has been considerable concern expressed about the types of influence that investor-owned hospitals might attempt to exert over physician practice behavior in pursuit of their profit objectives. Table 3 reports information from the first quarter 1984 SMS survey comparing the extent to which physicians in proprietary and nonproprietary hospitals are subject to several different types of programs that may have this intent.

Among physicians responding to the survey, those in nonproprietary hospitals, more often than those in proprietary hospitals, face guidelines designed to reduce lengths of stay (71.8% compared to 65.9%) and post-discharge length of stay review programs (90.1% compared to 84.9%), but are less often subject to programs that formally review clinical decisions (79.8% compared to 83.0%). Among physicians who indicated their hospital has set guidelines to reduce the length of patient stay, those in nonproprietary hospitals were more likely to have experienced attempts by the hospital to limit their use of the hospital in other respects. These include efforts to reduce the number of diagnostic tests and treatment procedures physicians order, as well as reductions in the overall range of services provided. However, none of the differences shown in Table 3 are statistically significant.

---

*The active medical staff is generally responsible for the preponderance of medical practice within the hospital and the performance of all significant medical staff organization and administrative functions. The associate medical staff is comprised of those physicians being considered for advancement to the active medical staff.

Table 3
PERCENT OF PHYSICIANS REPORTING HOSPITAL PROGRAMS TO INFLUENCE THEIR PRACTICES BY TYPE OF HOSPITAL AT WHICH PHYSICIANS ADMIT MOST PATIENTS*

	Proprietary Hospitals	*Nonproprietary Hospitals*
Hospital sets guidelines to reduce length of stay	65.9	71.8
Hospital review length of stay after discharge	84.9	90.1
Hospital formally review clinical decisions	83.0	79.8
Physicians in hospitals that set guidelines to reduce the length of stay:		
Hospital has attempted to reduce the number of diagnostic tests you order	39.8	41.1
Hospital has attempted to reduce the number of treatment procedures you prescribe	26.7	32.2
Hospital has reduced the range of services it provides	6.7	9.5

*No differences between proprietary and nonproprietary hospitals shown in the table are statistically significant.

SOURCE: American Medical Association, First Quarter 1984 Socioeconomic Monitoring System Survey.

This indicates that, at least for the specific types of programs considered, proprietary and nonproprietary are about equally likely to attempt to influence physician practice behavior.

Conclusion

This report has summarized the Council's findings related to the extent of physicians' involvement with proprietary hospitals, and the characteristics of physicians' practice in both proprietary and nonproprietary institutions.

The evidence presented reveals no significant differences between physicians in proprietary and nonproprietary hospitals. This suggests that competitive pressures may be working to create relatively similar environments for physicians in both types of hospitals.

The Council will continue to monitor developments relating to competition in medicine. In its prior reports, the Council has provided an overview of the general effects of competition, in addition to discussing many specific concerns relating to the increasingly competitive environment of medicine. Rather than continuing to treat competition as a general subject in future reports, the Council, as in this report, will focus its efforts on considering some of the specific effects of competition in more detail and providing separate reports on these effects. This will make it possible to provide more in-depth analysis of the specific effects of competition.

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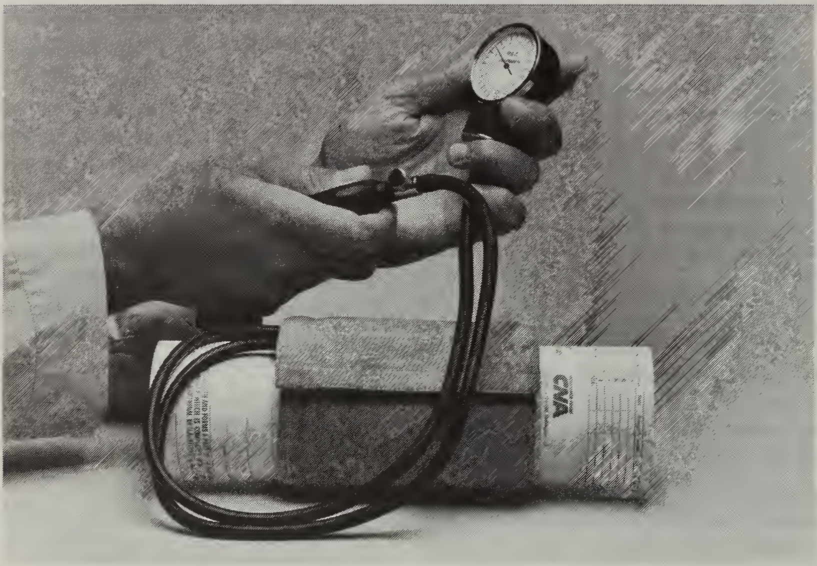

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1984 Interim AMA-MSS Meeting: My Impression

ERIC F. BERNSTEIN

My mind wandered as I flew to California, the first stage on my way to the AMA-MSS (American Medical Association-Medical Student Section) Interim Meeting in Honolulu. This was to be the first AMA-MSS meeting I would attend. Only two hours before I had been finishing last minute business as a medical student at the West Haven Veterans' Administration (VA) Hospital. Now I was in a nice, comfortable seat 28,000 feet above the ground reviewing issues to be discussed at a meeting thousands of miles away. The idea that what went on at the meeting could actually be translated into changes at the VA, a place where time seems to stand still, was enough to make a skeptic of even the most devoted MSS member. Still, I have a need to have input into the evolving field of medicine, and this seemed an intelligent place to start.

My next concern was how I could actually contribute without full knowledge of the Code of Sturgis (used to run meetings according to parliamentary procedure). Would I be able to state a point, ask a question or even use the rest room without being out of order, or would only those experienced members be allowed to participate? The skills and fund of knowledge necessary to function as a clinical clerk in medicine were very different from those needed by a representative at the AMA-MSS Interim Meeting. At this point, the middle of my first rotation in Internal Medicine enroute to my first AMA-MSS conference, I felt deficient in both.

Although I was inexperienced at dealing with the procedural aspects of the meeting, I had spent many hours discussing the different issues we had considered. Every student had certainly dealt with most of these at one point in their training. Non-members frequently criticized the AMA-MSS for dealing with "political" or "economic" issues unimportant to them, yet these concerns touch every medical student in the country.

Issues such as mandatory seat belt legislation, the labeling of alcoholic beverages as dangerous and the advertising of tobacco products were a few of the many resolutions discussed. After a few weeks at the VA Hospital, I had seen enough of the effects of the latter to form a strong opinion about them. The MSS also organized to write the Secretary of Education to raise the level of Guaranteed Student Loans. In the face of increasing tuitions this would certainly affect a large number of students. A proposal to endorse subsidized Hepatitis B vaccine for students was among the resolutions. A resolution to study the effect of on call shifts exceeding 24 hours on patient care and medical student and resident education must certainly be listed as an issue relevant to students, and deserving of their input.

Picture a distinguished professor lecturing to my class, about 100 third-year medical students. Suddenly he becomes short of breath, clutches his chest, and drops to the floor. Unfortunately, he picked the wrong group to experience his myocardial infarction in front of. You see, we only had one CPR session which was organized by a student and our certification has expired. If we fail to seek this training independently, we may all graduate as M.D.'s knowing about atherosclerotic disease and CAT scans but having to rely on boy scouts for first-aid at the scene of an accident. AMA Resolution 25 introduced by Elna Masuda for the California Delegation: "RESOLVED, that the AMA investigate the lack of adequate first aid and CPR training in medical schools; and be it further RESOLVED that the AMA recommended that medical schools in cooperation with the American Red Cross or American Heart Association provide first aid and CPR training to medical students early in their medical education." Although students would take different sides on the various issues, few would dispute the importance or relevance of these resolutions to their lives as students.

Upon arrival in Honolulu I found the registration process was very well organized and allowed representatives to be credentialled so the meeting could start on time. Remarkably, almost every meeting and event started according to schedule. Even more surprising was the fact

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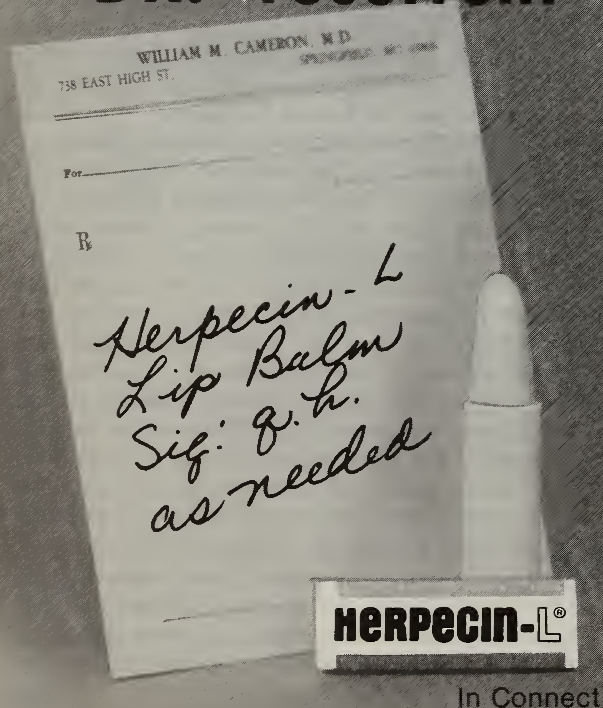
ERIC F. BERNSTEIN, 3rd year medical student Yale University School of Medicine.

that the complex Code of Sturgis was not so complex and actually functioned to increase the efficiency of the meetings. Representatives proceeding out of order were merely corrected and allowed to continue, while complex points of procedure were explained with or without being questioned. The whole system functioned in sharp contrast to most bureaucracies by simplifying proceedings and creating a comfortable environment which encouraged student input.

Despite all the issues to be discussed, proceedings and work to be done, it was nice to know that while I was in Hawaii, I was with a group of people that knew how to have fun too. Doctors are excellent at prescribing rest, healthy diets and exercise, but are notoriously delinquent at making time for such necessities. One VA patient candidly pointed this out to me after my statement that a full diet and some well needed rest were all he required to be on his way home. He pointed to the bags under my eyes and the Hershey bar in my pocket and said that I should "practice what I preach" if I ever wished to reach his age in as fine condition as he. At night we had scheduled receptions, a catamaran cruise and a few unscheduled excursions, all of which provided necessary diversions after the day's proceedings.

The AMA-MSS meeting provided me with an opportunity to exchange ideas with other medical students from all over the country on issues which pertained to us specifically and to medicine as a whole. I saw that the AMA takes student input seriously and encourages their participation making students' voices heard within the AMA.

Dx: recurrent herpes labialis



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Month in Washington

Ban on Cigarette Ads

A coalition of health organizations this month has asked the Federal Trade Commission (FTC) to take action against a recent series of advertisements which contend that the link between smoking and disease is opinion, not scientific fact.

At a news conference, in Washington DC, spokesmen for the American Heart Association, the American Lung Association and the American Cancer Association called the R.J. Reynolds Tobacco Co. advertisements "false and deceptive."

"The R.J. Reynolds ad is a blatant attempt to mislead the public on the relationship between cigarette smoking and cardiovascular disease," said John Holbrook, M.D., of the American Heart Association.

"We urge the FTC to put a stop to this deceptive and self-serving campaign by R.J. Reynolds. What Americans don't know about smoking is literally killing them," said Alfred Munzer, M.D., of the American Lung Association.

R.J. Reynolds has run more than 20 "public issue" advertisements in national magazines and newspapers since early last year. The most recent advertisement attacks the Multiple Risk Factor Intervention Trial (MRFIT), claiming no significant decline in risk of heart disease in men who quit cigarette smoking.

Lewis Kuller, M.D., one of the principal investigators of the MRFIT, said that on the contrary the study found that men who quit smoking had a coronary death rate almost 50% below those who continued to smoke. The study did not intend to examine whether cigarette smoking was a cause of heart disease; in fact, the scientific evidence is now conclusive and need not be re-examined, he said.

The coalition asked the FTC to require that R.J. Reynolds pay for corrective advertisements which would support the conclusion that smoking causes coronary heart disease. In addition, it urged newspapers and magazines to stop printing the R. J. Reynolds ads or print their counter ad called "The Science of Selling Cigarettes."

A spokesman for the tobacco company accused the health groups of trying to use a government agency to "stifle those who wish to speak out with another point of view." R.J. Reynolds is prepared to answer any questions the FTC may have about their advertisements, they said.

In 1983, the US Surgeon General called smoking "the most important of the known modifiable risk factors for coronary heart disease in the United States." Cigarette smoking has been linked with an increased risk of dying for over 20 years.

* * * *

Hospital Data to be Made Public

The government has issued a final rule that would give the public access to hospital statistics collected by peer review organizations (PROs).

The statistics would identify individual hospitals but not individual physicians.

In issuing its new rule, the Health Care Financing Administration (HCFA) rejected arguments from some business and consumer groups—including the Washington Business Group on Health and Ralph Nader's Health Research Group—that PROs should also be required to release physician-specific data.

The American Hospital Association and the American Medical Association had argued on the other hand that the final rule should scale back a proposed requirement that PROs release hospital-specific data. They argued that such information was misleading because it did not take into account the fact that some hospitals traditionally treat sicker patients.

These changes, too, were rejected by HCFA, and the final rule states that PROs "are an important source of information to aid consumers and consumer organizations in reaching informed decisions about the types of health care services that are offered." Information could include, for instance, mortality rates, costs, length of stay, volume, or infection rates by hospital or hospital department. Individual patient records may not be disclosed.

Prepared by the Washington, D.C. Office of the American Medical Association.

Some modifications allow hospitals an opportunity to explain its statistics, however. The PRO must give the hospital 30 days to comment before disclosing data and must include the hospitals, comments with information that it releases. Another modification will permit researchers to have access only to the data the public has.

Representatives of the American Medical Peer Review Association, which represents many of the PROs, are unhappy with this change since it appears to have a detrimental effect on a research wing AMPRA has just set up. One goal of the research was to be the development of better quality of care measures and AMPRA officials believe they need physician specific data to accomplish this.

The "confidentiality" rule was one of four final regulations just issued by HCFA. The other rules govern the conduct of review, the appeals process, and sanctions under the PRO program. All have been due for months and widespread Washington rumor had suggested that the major hold up in the four sets of rules involved debate within the Administration over the release of the physician-specific information. The Office of Management and Budget was said to favor the release of the more specific information.

* * * *

'Quality' Focus of New House Bill

Contending that Medicare "cost containment" is in danger of becoming "care containment," House Aging Committee Chairman Rep. Edward Roybal (D-CA) has introduced legislation to expand quality review activities of the program's peer review organizations (PROs).

Called the Quality Assurance Reform Act of 1985 (HR 1970), Roybal's bill would require the PROs to devote as much time and resources to monitoring quality as costs and would extend PRO review to all Medicare services, including those in physicians' offices.

The bill, which follows Aging Committee hearings focusing on potential quality problems in Medicare's prospective pricing system, would:

- require that as of October 1, 1986, HHS stipulate in its award, administration and evaluation of PRO contracts that at least half of the PROs efforts are to be directed to quality review.
- extend PRO review to physicians offices, nursing homes, home health agencies, and other providers by April 1, 1988.
- direct PROs to maintain 24 hour hot lines for questions and complaints from Medicare providers and beneficiaries.
- require each PRO to have five-to-seven member Consumer Advisory Board by October 1, 1986.
- direct the Congressional Office of Technology Assessment to appoint a nine-member National Council on Quality Assurance.
- increase PRO funding as compared to current law and adjusted for inflation, by 30% in 1986, 40% in 1987, and 50% in 1988 and subsequent years.

House Sentiment Builds Against Physician Fee Freeze

An opening round of debate in the House of Representatives over the Reagan Administration's fiscal 1986 budget proposals indicated strong sentiment for softening the President's proposal to continue a Medicare freeze on all physician fees.

In three days of hearings before the House Ways and Means Health Subcommittee, only Health Care Financing Administration head Carolyne Davis, Ph.D., defended a budget proposal to continue the physician fee freeze for all physicians. American Medical Association President-elect Harrison Rogers, M.D., said the proposal was "discriminatory and counterproductive." Rep. Willis Gradison (R-OH) called it a "breech of faith." And Subcommittee Chairman Fortney (Pete) Stark (D-CA) said he "does not intend to support postponing the fee increase" for those who signed participating agreements.

Several subcommittee members also indicated that they are considering several alternatives to the President's budget proposals. In addition to modifying the physicians freeze, these include mandating second surgical opinions for Medicare, freezing Medicare reimbursement of hospital capital expenditures and requiring some income-related cost increases for beneficiaries.

Some members, including Stark and Gradison and New York Democrat Charles Rangel, revealed substantial irritation over HCFA's failure to produce a number of reports Congress needs to make refinements in the new Medicare prospective pricing system. One such report, due in December, was to define and list hospitals that treat "disproportionate shares" of indigent patients.

Congress has indicated several times that it believes prospective rates for these hospitals should be adjusted and Stark is now working with the American Hospital Association to try to devise his own list of "disproportionate share" hospitals.

Despite repeated assertions that Medicare cuts might be acceptable as part of an across-the-board budget freeze—including defense spending and addressing some tax "loopholes"—some 20 witnesses unanimously opposed the President's present budget plan. They noted that Medicare has been cut by $25-30 billion over the past five years and suggested that changes in the system are threatening the prospective pricing system by destroying providers' faith in the government promises and eroding confidence in the quality of care.

In her defense of the physician freeze. HCFA's Davis maintained that the freeze delays (but does not break) a promise that physicians who signed participating agreements would have their fee profiles updated in October of 1985. The HCFA Administrator also said the budget anticipates that physicians will increase the volume of services they provide each patient by about 3%.

Dr. Rogers, a general surgeon from Atlanta, said that the only freeze Congress imposed in its last budget cycle was on physicians. He maintained that continuation of the freeze "would extend an unfair and extremely discriminatory practice" because "only physicians would be subjected to a two-year freeze." A continuation of the freeze, he said, would mean that Medicare payments to physicians in 1986 will be based on 1982 charges and "may prove counter-productive" since it could "discourage physicians from accepting assignment" and "treating Medicare patients." Furthermore, he said, it penalizes the 80% of physicians who responded to the AMA's call for a voluntary freeze on charges to all patients.

Responding to Dr. Rogers' comments, Rep. Stark observed that "although I rarely agree with the AMA, I just want them to know that for those physicians that responsibly accepted voluntary assignment, I think we ought to fulfill the promise that their fees would be allowed to rise."

* * * *

Medicare Bankruptcy Not Seen Until Near 2000

Medicare's hospital insurance fund is not likely to go bankrupt until 1998, according to the latest government report on the status of Medicare and Social Security.

The report from the Social Security Trustees also concludes that Medicare's supplementary medical insurance trust fund is "financially sound." A 1982 report predicted bankruptcy of the hospital fund by 1987 and last year's report anticipated bankruptcy in 1991.

In announcing the trustee's findings, Department of Health and Human Services Secretary Margaret Heckler attributed the improved condition of the hospital fund to "lower health care inflation and increased efficiency among health care providers, spurred in part by changes in Medicare policy."

The Secretary warned against Congressional complacency on Medicare reform, however, and said "good faith and strong medicine" will be required "in the months and years ahead."

The new projections assume enactment of the President's proposal to freeze hospital rates in 1986, and the trustees urged Congress to "take action to curtail" the rate of growth in both the hospital and supplemental medical funds.

At the end of calendar 1984 the hospital fund had a balance of $15.7 billion, $2.6 billion higher than had been predicted in last year's report. Under the trustees' most pessimistic economic assumption, the fund would remain in the black until 1992. Under the most optimistic assumption, the fund would remain healthy for at least the remainder of this century.

Under the moderate or middle range economic assumptions seen as most likely, the fund would climb steadily until it peaks at $76.3 billion in 1992 and then decline into insolvency by 1998. To produce long-term stability and keep the fund solvent over the next 25 years under this projection would require that benefits be reduced 19% or Medicare contributions increased 24%.

Unlike the hospital fund, which is financed through a payroll tax (set at 1.35% of earnings up to $39,600 this year), the supplemental medical insurance is financed through general revenues and premiums. In 1984, the program covered 29.4 million people and general revenue contributions amounted to $17.1 billion or 73.6% of all SMI income. About 22.3% of income came from premiums paid by the beneficiaries and the remainder came from interest payments on the SMI fund.

* * * *

PRO Progress Assessed by Congress

Nearly half of the nation's 54 Medicare Peer Review Organizations (PROs) have negotiated alterations in the cost and quality goals they agreed to in their contracts with the federal government.

In announcing what Medicare officials are calling "refinements" in the PRO's contract objectives, Health Care Financing Administration head Carolyne Davis, Ph.D., told a Senate subcommittee that 25 PROs have already negotiated changes and negotiations are continuing in several other states—including Rhode Island, Maine, Montana, and Wyoming.

Davis' announcement, which came at a hearing of the Senate Finance Health Subcommittee, appeared to reinforce earlier HCFA claims that the numerical objectives in the PRO contracts were not intended as quotas and were subject to change if more experience and data indicated change was warranted.

In addition to the contract changes, the HCFA Administrator also reported that four sets of long-delayed final PRO regulations had finally been released, that a Super-PRO contract to evaluate the PROs will be awarded by the end of June, and that her agency is planning pilot programs using concurrent review to prevent premature hospital discharges and to test PRO review of outpatient services.

Although the publication of the final regulations and the announcement of widespread contract renegotiations appeared to have blunted last summer's heated charges that the PRO objectives constitute arbitrary quotas, American Medical Association representative William Felts, M.D., and American Hospital Association Executive Vice President Jack Owen complained that delays in issuing the regulations have created situations harmful to physician and hospital relationships with PROs.

American Medical Peer Review Association President Howard Strawcutter, M.D., reported, however, that while PROs think HCFA is too concerned with the details and process of PRO operation, overall implementation of the program has gone well.

Sen. David Durenberger (R-MN), who crafted the law creating the PROs, remains concerned nevertheless about several other issues facing the PROs. These include OMB's "continued resistance" to the PROs, periodic reports of quality problems such as premature discharges, and a fear that outpatient services may be eating up much of the savings.

Like Durenberger, who emphasized that Congress view PROs as "Medicare's vehicles to assure quality," witnesses generally called for increased emphasis on and further improvements in the quality objectives of the PROs. Both the Senator and the professional groups urged HCFA to solicit professional and public input as contracts are redrawn and renegotiated about a year from now. All are viewing the Super-PRO contract as an important part of that process.

HCFA official Phil Nathanson assured the subcommittee that the agency will have at least two semi-annual Super-PRO reports in hand before it begins to evaluate the PROs performance. But most witnesses were critical of the delay in awarding the contract which was withdrawn, redesigned and reissued after initial bids from the American Medical Association and three other organizations were determined to cost more than HCFA had available for the contracts.

Willis Goldbeck of the Washington Business Group on Health blasted the idea of the AMA evaluating the PROs as a conflict of interest. But Dr. Felts reported that the AMA will respond to the new bid proposal and will continue to oversee the PRO's progress through a new monitoring program, even if the Super-PRO contract is awarded to another bidder.

* * * *

Taking the Stick to Graduate Medical Education

Federal budgetary pressures, a predicted surplus of physicians and cost-conscious insurers and businesses are forcing medical educators to reassess both the funding and the makeup of the graduate medical education system.

Funded primarily through patient revenues, the design of the system—widely acknowledged as one of the world's finest but frequently accused of turning out an army of specialists in a world that needs more primary care physicians—until now has been left largely in the hands of physicians and the medical schools and hospitals which train them. Federal attempts to influence graduate medical education were limited to the carrot approach as various subsidies were offered to encourage the graduate training of primary care physicians.

But the national debate that initially focused simply on curbing Medicare spending has now been expanded to include the possibility of using Medicare as a stick to shape graduate medical education.

The Reagan Administration has proposed to cut Medicare payments for medical education and eliminate all federal grants for health professions training.

Sen. Dan Quayle (R-IN), who has suggested a plan that would provide Medicare reimbursement only to training programs in which at least 70% of residency positions were in primary care and at least 75% of the residents were graduates of American schools approved by the Liaison Committee on Medical Education. The plan, which Quayle outlined at a hearing of the Senate Labor and Human Resources Committee, would also require that hospitals and other teaching programs have an affiliation with a medical school. The 70/30% ratio of primary care to specialty physicians might be applied to some larger base than individual institutions, and a national commission would be set up to determine whether the ratio is appropriate and to recommend changes in the future.

A number of other Congressmen are also designing proposals to modify Medicare's approach to graduate education costs. At an April hearing of the House Commerce Committee Health Subcommittee Chairman Rep. Henry Waxman (D-CA) pointedly contrasted the "cost-based and open-ended" Medicare and Medicaid approach with "limited" and "sharply focused" federal grants for health professions training.

Other Senate players in addition to Quayle include Majority Leader Robert Dole (R-KS) and Finance Health Subcommittee Chairman David Durenberger (R-MN). Durenberger, who sparked Congressional interest in medical education funding last fall, has backed away from a block grant approach he introduced at that time. He is now working with Dole and Sen. Lloyd Bentsen (D-TX) to design an alternative to the President's budget proposals. As an alternative to the Reagan Administration's proposal to halve the current 11.59% factor Medicare uses to adjust payments for indirect costs of medical education, the Senators reportedly have considered a 9% factor. As one possible alternative to the President's proposed freeze on payments for the direct costs of medical education, they have considered a plan advanced by Johns Hopkins University President Robert Heysell, M.D., to limit Medicare funding for graduate training to some "finite period," such as three years.

The Heysell proposal has also caught the attention of Quayle and Waxman and been recognized by the Association of American Medical Colleges as one of several alternatives that might be pursued. The AAMC and other key players have been reluctant to recommend or endorse a particular solution, however, and the confusion and Congressional interest have spawned a multitude of studies and task forces. The AAMC, the AMA and the AHA have formed separate advisory committees on the subject and have held some joint meetings. Thus far, however, these meetings appear to have been more successful at delineating areas of difference than agreement.

In the face of such controversy, all the involved groups are urging the legislators not to take what AMA representative Robert Stone, M.D., termed "precipitous action that could undermine not only our graduate medical education system but the quality of our health system as a whole."

FTC Issue Appears to Fade

The AMA vs. FTC feud over regulation of professionals, once a subject of heated debate, has receded from prominance.

In 1982, it prompted congressional dispute and widespread media publicity; last month, it received only mild attention from committees in the House and Senate, a couple of newspaper reporters, and a handful of high school students on tours through Congress.

Two factors are credited with the change in mood; first, a recent Supreme Court ruling that clarified the role of state regulations in antitrust cases and, second improved communication between the AMA and the FTC over areas of professional self-regulation and discipline.

Because of these new developments, the AMA will no longer push for a professions provision spelling out FTC's authority. Neither will the American Bar Association press that earlier position.

"It is no longer necessary to adopt specific language concerning the professions," AMA president Joseph F. Boyle, M.D., told Sen. Robert W. Kasten Jr. (R-WI) of the Consumer Subcommittee of the Senate Committee on Commerce, Science and Transportation on hearings about FTC Reauthorization. "On the contrary, we feel that such language could be counterproductive as establishing rigid limits in a period of mutual discussion and evolving law."

The FTC, for its part, has become increasingly willing to recognize the role of self-regulation by physicians. The FTC has said it supports self-policing and discipline of physician by groups such as the AMA, but will continue to monitor professional conduct over anti-competitive practices, price fixing, fraud, deceptive advertising, and restraints on trade. Unlike the AMA, the FTC still seeks specific language that would spell out its authority over professionals.

The conciliation, if adopted by Congress, means that anti-trust disputes about state regulation of professionals will end up being resolved in court rather than being set by statute. This change is accepted by both the AMA and traditional adversaries such as Congress Watch.

In addition, the Supreme Court decision *Southern Motor Carriers* case provided importance guidance about the application of anti-trust laws to state-supervised activities.

The Supreme Court decision in the recent *Southern Motor Carriers* case was significant because it loosens conditions under which the professions are covered by state laws and thus protected from FTC intervention, according to AMA's testimony. In the past, the FTC would steer clear of anti-trust situations that were part of an active, "compulsive" state policy—for instance, situations in which a state forced professionals to set certain prices. The *Southern Motor Carriers* decision says that there doesn't have to be evidence that a state forced professions to set rates—only that the state allowed professions to set rates.

For instance, the decision may insulate doctors in the Maine Medical Society who meet with members of the state Medicaid board to discuss fee structure. Although the state does not require that these groups meet, it allows them to—and hence would protect them from FTC regulation.

In fact, the language of the professions amendment could actually be counterproductive, said Dr. Boyle, by inhibiting disciplinary actions by professional groups against negligent physicians. "State boards are able to identify negligent physicians and have the opportunity to exert discipline. . . But there is the perception that this would be interfered with by restrictive language."

The professions language is supported by the nurses and opticians employed by chain drug stores. Recent FTC actions—such as the "Eyeglasses I" and "Eyeglasses II" rules that removed restrictions on advertising and the release of prescription to a patient—have helped keep down costs, the opticians said. The position also is opposed, although for different reasons, by the dentists. The American Dental Association witness predicted that an "overzealous" FTC will see no limit on its authority over state laws; Congress should define the FTC's authority to invalidate state laws, he said.

* * * *

Feds Urge DPT Shots

Physicians should resume giving the complete DPT schedule of vaccines to the 2 million children whose shots had been postponed during the recent vaccine shortage, federal officials have announced.

On April 25, Connaught Laboratories once again offered full-scale distribution of the vaccine, ending the shortage. An estimated 2.2 million doses now are ready for immediate shipment to doctors and public health officials.

Because of the shortage, the Public Health Service asked physicians to postpone administering the fourth and fifth doses of the vaccine, usually given to children 18 months and 4 to 6 years of age. Now, supplies are adequate to meet national needs.

It is especially important to provide the DPT vaccine to children scheduled to enter kindergarten or first grade this fall, PHS officials say.

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Nosocomial Infection Surveillance, 1983

CENTERS FOR DISEASE CONTROL

Introduction

Nosocomial infections are an important cause of morbidity and mortality in hospitalized patients; approximately 5%-6% of hospitalized patients develop nosocomial infections.[1] These infections result in a prolongation of hospitalization and cost over a billion dollars a year.[2] The National Nosocomial Infections Study (NNIS) has collected and analyzed data on the frequency of nosocomial infections in United States hospitals since 1970. This report provides descriptive data on nosocomial infections in a sample of U.S. hospitals in 1983.

Materials and Methods

The methods of this study and characteristics of participating hospitals have been described in detail.[3] In brief, hospitals participating in NNIS conduct active hospital-wide surveillance using uniform definitions of nosocomial infections. During 1983, 54 hospitals regularly (≥8 months) reported data to CDC. For each nosocomial infection detected, the following information was reported: site of infection, date of onset, whether the infection was associated with a surgical procedure, the pathogen(s) isolated, occurrence of secondary bacteremia, antimicrobial susceptibility of bacterial pathogens, service of the patient, and, for those patients who died with a nosocomial infection, the relationship of the infection to death. In addition, the hospitals reported the number of patients discharged each month from the six primary services: medicine, surgery, obstetrics, gynecology, pediatrics, and newborn.

Data are recorded on standardized forms, which are sent to CDC each month. When the data are received at CDC, they are coded, entered into a computer, and edited before being analyzed.

Results

The NNIS Sample. The hospitals participating in NNIS are not a probability sample of U.S. hospitals; however, the 54 hospitals that reported data regularly in 1983 range in size from 80 to over 1,200 beds, are located throughout the United States, and include hospitals owned by state and local governments, as well as by profit and non-profit organizations. The geographic distribution of the 54 hospitals among the four regions of the country (Northeast, North Central, South, West) is roughly the same as for all 6,053 U.S. hospitals included in the American Hospital Association Annual Survey of Hospitals.[4] Hospitals affiliated with medical schools, referred to as teaching hospitals, are still greatly over-represented among the NNIS hospitals; 56% (30/54) of the NNIS hospitals are teaching hospitals, whereas only 14% of the hospitals across the country are affiliated with medical schools. Similarly, the 54 NNIS hospitals tend to be large, with a median size of 407 beds, compared with a median size of only 110 beds for the 6,053 U.S. hospitals.

Despite these limitations, previous analyses have shown that data collected in NNIS can be usefully interpreted by stratifying the 54 reporting hospitals into three categories: 1) non-teaching hospitals, 2) small teaching hospitals (500 or fewer beds), and 3) large teaching hospitals (more than 500 beds).[3]

The infection rates (number of hospital-acquired infections/thousand patients discharged) were highest in the large teaching hospitals and lowest in the non-teaching hospitals, as were the infection rates on each of the six services. In all three categories of hospital, the infection rate was highest on the surgery service (SURG), followed generally by medicine (MED), gynecology (GYN), and obstetrics (OB). The one exception was in the small teaching hospitals, where the infection rates on the medicine and gynecology services were similar. Lowest infection rates were reported on the newborn (NEW) and pediatrics (PED) services.

The urinary tract was the most frequent site of infection,

WILLIAM R. JARVIS, M.D.; JOHN W. WHITE, PH.D.; VAN P. MUNN, B.S.; JANET L. MOSSER, R.R.A.; T. GRACE EMORI, R.N., M.S.; DAVID H. CULVER, PH.D.; CLYDE THORNSBERRY, PH.D.; JAMES M. HUGHES, M.D.; Hospital Infections Program, Center for Infectious Diseases.

followed by surgical wounds and lower respiratory tract in all three hospital categories. On each service and for each site of infection, the infection rates were highest in the large teaching hospitals and lowest in the non-teaching hospitals.

In all three hospital categories, infections of the urinary tract, surgical wounds, and lower respiratory tract accounted for over 70% of the infections. Primary bacteremia accounted for a higher percentage of infections in the large teaching hospitals than in the other hospitals.

Combined Rates by Service and Site. In general, the site-specific infection rate within each service was highest in the large teaching hospitals and lowest in the non-teaching hospitals. The site-specific infection rates by service show that for each hospital category, urinary tract infections occurred predominantly on the surgery, medicine, and gynecology services. Surgical wound infections occurred predominantly on the surgery, obstetrics, and gynecology services. Lower respiratory infections occurred predominantly on the medicine and surgery services. Primary bacteremia occurred primarily on the surgery, medicine, and newborn services. Cutaneous infections occurred primarily on the newborn service.

Pathogens. Of the 28,248 infections reported, 66% were caused by single pathogens, and 19% were caused by multiple pathogens. No pathogen was identified in 5% of the infections, and no culture was obtained in 10%. Of the 85% of infections in which pathogens were identified, 86% were caused by aerobic bacteria, 2% by anaerobic bacteria, and 7% by fungi. Together viruses, protozoa, and parasites accounted for 5% of the infections of known etiology. *Escherichia coli, Staphylococcus aureus,* enterococci, and *Pseudomonas aeruginosa* were the most frequently reported pathogens. *E. coli* was the most frequently reported pathogen on the medicine, surgery, obstetrics, and gynecology services; *S. aureus* was the most frequently reported pathogen on the pediatrics and newborn services. *P. aeruginosa* was the second most frequently identified pathogen on both the medicine and surgery services and was less frequent on the other four services; enterococci were the second most frequently identified pathogens on the obstetrics and gynecology services and third most frequently identified on the medicine and surgery services; coagulase-negative staphylococci were the second most frequently identified pathogens on the pediatrics and newborn services and fourth most frequently identified on the obstetrics service.

E. coli was the pathogen most frequently associated with urinary tract infections, followed by enterococci, *P. aeruginosa, Klebsiella* spp., and *Proteus* spp. *S. aureus* was the pathogen most frequently associated with surgical wound infections, followed by enterococci, *E. coli,* coagulase-negative staphylococci, and *P. aeruginosa. P. aeruginosa* was the pathogen most frequently associated with lower respiratory tract infections, followed by *S. aureus, Klebsiella* spp., *Enterobacter* spp., and *E. coli.* Coagulase-negative staphylococci were the pathogens most frequently associated with primary bacteremia, followed by *S. aureus, E. coli, Klebsiella* spp., and enterococci.

When the pathogens causing infections at the five major sites were examined by service, interesting differences were noted (Table 1). On the surgery and medicine services, *E. coli, P. aeruginosa,* enterococci, and *S. aureus* were the pathogens most frequently isolated. On the gynecology and obstetrics, *E. coli* and enterococci were the most frequently identified pathogens. These were followed by *S. aureus* and *Klebsiella* spp. on the gynecology service and by group B *Streptococcus* and *S. aureus* on the obstetrics service. On the pediatrics and newborn services, *S. aureus,* coagulase-negative staphylococci, and *E. coli* were the most frequently isolated pathogens, followed by *Candida* spp., *Klebsiella* spp., and *P. aeruginosa* on the pediatrics service and by group B *Streptococcus, Klebsiella* spp., and *P. aeruginosa* on the newborn services. On all six services, *E. coli* was the pathogen most frequently isolated from the urinary tract, with enterococci second on the medicine, obstetrics, and gynecology services and *P. aeruginosa, Klebsiella* spp., and *Candida* spp. second on the surgery, newborn, and pediatrics, respectively. *S. aureus* was the pathogen most frequently associated with surgical wound infections on all services except gynecology, where *E. coli* was isolated most frequently. The pathogen most frequently associated with lower respiratory infections varied by service; *P. aeruginosa* on the surgery and medicine services, *S. aureus* on the obstetrics and newborn services, and *Klebsiella* spp. on the gynecology and pediatrics services. Coagulase-negative staphylococci were most frequently associated with primary bacteremia on the pediatrics, newborn, and surgery services. In contrast, *S. aureus,* group B *Streptococcus, and Bacteroides* spp. were the pathogens most frequently associated with bacteremia on the medicine, obstetrics, and gynecology services, respectively.

Secondary Bacteremia. Secondary bacteremia was defined as a bloodstream infection with an organism that was also isolated from an infection at another site. Secondary bacteremia was reported most frequently by large teaching hospitals and least frequently by non-teaching hospitals. Secondary bacteremia occurred most frequently on the pediatrics service, followed by the newborn and medicine services, and least frequently on the obstetrics and gynecology services. It was reported less frequently with infections of the urinary tract, surgical wounds, lower respiratory tract, and cutaneous infections than with infections, collectively, at “other” sites. With respect to the five major sites, secondary bacteremia occurred least frequently following urinary tract infections. It occurred most frequently following infections caused by *Bacteroides* spp., *Serratia* spp., *S. aureus, Acinetobacter* spp., group B *Streptococcus, and Providencia* spp. (Table 2).

Table 1
Five most common pathogens isolated and percentage of total within each site and service, 1983

Service	Site									
	UTI		SWI		LRI		CUT		BACT	
	Pathogen	%	Pathogen	%	Pathogen	%	Pathogen	%	Pathogen	%
Medicine	*E. coli*	32.7	*S. aureus*	15.7	*P. aeruginosa*	14.7	*S. aureus*	29.0	*S. aureus*	14.7
	Enterococci	14.2	Enterococci	13.4	*S. aureus*	14.1	Coag-neg *Staph.*	9.7	Coag-neg *Staph.*	13.9
	P. aeruginosa	11.1	*E. coli*	11.1	*Klebsiella* spp.	13.3	*P. aeruginosa*	8.9	*E. coli*	10.7
	Klebsiella spp.	8.2	*P. aeruginosa*	10.8	*Enterobacter* spp.	9.2	*Enterobacter* spp.	7.5	*Klebsiella* spp.	10.6
	Proteus spp.	8.0	*Enterobacter* spp.	8.0	*E. coli*	7.5	*E. coli*	7.1	*P. aeruginosa*	7.5
Surgery	*E. coli*	28.6	*S. aureus*	19.6	*P. aeruginosa*	15.6	*S. aureus*	19.2	Coag-neg *Staph.*	13.1
	P. aeruginosa	16.2	Enterococci	11.3	*Klebsiella* spp.	12.4	Enterococci	13.5	*S. aureus*	12.0
	Enterococci	14.4	*E. coli*	10.9	*Enterobacter* spp.	11.4	*P. aeruginosa*	10.0	*Enterobacter* spp.	10.3
	Klebsiella spp.	7.3	*P. aeruginosa*	9.0	*S. aureus*	11.1	Coag-neg *Staph.*	8.9	Enterococci	9.6
	Proteus spp.	7.1	Coag-neg *Staph.*	8.4	*E. coli*	6.9	*E. coli*	8.0	*E. coli*	8.8
Gynecology	*E. coli*	43.7	*E. coli*	17.2	*Klebsiella* spp.	17.2	Enterococci	25.0	*Bacteroides* spp.	14.7
	Enterococci	20.2	*S. aureus*	16.6	*S. aureus*	17.2	*E. coli*	20.8	Klebsiella spp.	11.8
	Klebsiella spp.	6.1	Enterococci	13.8	*P. aeruginosa*	10.3	*S. aureus*	20.8	*E. coli*	8.8
	Proteus spp.	5.2	*Bacteroides* spp.	9.5	*Enterobacter* spp.	10.3	*Proteus* spp.	8.3	Coag-neg *Staph.*	5.9
	Group B *Strep.*	4.5	Coag-neg *Staph.*	7.4	*E. coli*	3.4	*Enterobacter* spp.	4.2	*Proteus* spp.	5.9
					Coag-neg *Staph.*	3.4				
					Group B *Strep.*	3.4				
Obstetrics	*E. coli*	35.1	*S. aureus*	14.5	*S. aureus*	12.5	*S. aureus*	35.6	Group B *Strep.*	22.2
	Enterococci	27.0	*E. coli*	13.6	*E. coli*	8.3	*E. coli*	17.8	*S. aureus*	11.1
	Group B *Strep.*	7.1	Enterococci	10.0	*Klebsiella* spp.	8.3	Coag-neg *Staph.*	11.1	Coag-neg *Staph.*	11.1
	Klebsiella spp.	4.8	Group B *Strep.*	9.5	Enterococci	4.2	Enterococci	8.9	*Bacteroides* spp.	11.1
	Proteus spp.	4.5	Coag-neg *Staph.*	9.1			*Proteus* spp.	6.7	Other anaerobes	8.9
							Klebsiella spp.	6.7		
Pediatrics	*E. coli*	38.6	*S. aureus*	28.8	*Klebsiella* spp.	16.7	*S. aureus*	35.2	Coag-neg *Staph.*	18.0
	Candida spp.	16.9	Coag-neg *Staph.*	16.4	*P. aeruginosa*	13.0	Coag-neg *Staph.*	14.8	*S. aureus*	12.4
	P. aeruginosa	10.8	*E. coli*	8.2	*S. aureus*	13.0	Enterococci	8.0	*Klebsiella* spp.	10.1
	Enterococci	8.4	*P. aeruginosa*	6.8	*Candida* spp.	7.4	*E. coli*	6.8	*E. coli*	9.0
	Klebsiella spp.	8.4	Enterococci	6.8	*E. coli*	3.7	*Candida* spp.	6.8	*Candida* spp.	6.7
			Klebsiella spp.	6.8			*P. aeruginosa*	6.8		
Newborn	*E. coli*	25.5	*S. aureus*	30.4	*S. aureus*	21.1	*S. aureus*	60.2	Coag-neg *Staph.*	22.0
	Klebsiella spp.	15.7	Coag-neg *Staph.*	26.1	*P. aeruginosa*	16.7	Coag-neg *Staph.*	9.2	Group B *Strep.*	19.6
	Enterococci	9.8	Enterococci	13.0	Coag-neg *Staph.*	12.3	*E. coli*	6.3	Enterococci	8.9
	S. aureus	7.8	*Klebsiella* spp.	13.0	*Klebsiella* spp.	11.4	Enterococci	6.3	*S. aureus*	7.1
	Enterobacter spp.	5.9	*P. aeruginosa*	8.7	*E. coli*	7.0	Klebsiella spp.	2.9	*E. coli*	6.0

Table 2
Ten pathogens with the highest percentage of associated secondary bacteremia, by hospital category, 1983

Pathogen	Non-teaching		Small teaching		Large teaching		All hospitals	
	Number of infections	Percentage with secondary bact.	Number of infections	Percentage with secondary bact.	Number of infections	Percentage with secondary bact.	Number of infections	Percentage with secondary bact.
Bacteroides spp.	24	16.7	65	13.8	53	17.0	142	15.5
Serratia spp.	123	9.8	115	10.4	241	13.7	479	11.9
S. aureus	648	7.7	828	8.6	1,274	16.0	2,750	11.8
Acinetobacter	26	0.0	27	0.0	94	18.1	147	11.6
Group B *Streptococcus*	57	7.0	87	8.0	100	16.0	244	11.1
Providencia spp.	14	7.1	13	7.7	19	15.8	46	10.9
Coagulase-negative *Staphylococcus*	212	4.2	356	6.5	550	9.5	1,118	7.5
Enterobacter spp.	285	5.3	321	4.2	601	9.7	1,207	7.4
Klebsiella spp.	366	4.4	404	4.2	718	9.7	1,488	6.9
P. aeruginosa	773	5.0	644	7.6	1,209	5.7	2,626	6.0

Antimicrobial Resistance. Resistance was defined as the number of resistant isolates divided by the number of organisms which were either sensitive or resistant. Methicillin-resistant *S. aureus* was most commonly reported from the large teaching hospitals. Compared with 1980-1982, however, methicillin-resistance in *S. aureus* increased in 1983 at non-teaching and small teaching hospitals and decreased slightly at large teaching hospitals.[3] Similarly the proportion of *S. aureus* organisms resistant to gentamicin increased at small teaching hospitals but decreased at large teaching hospitals.

The percentages of *E. coli, K. pneumoniae, S. marcescens,* and *P. aeruginosa* organisms that were resistant to aminoglycosides and selected beta-lactam antibiotics varied according to the three hospitals categories. Aminoglycoside resistance was most common in *P. aeruginosa* and *S. marcescens,* and cefotaxime or moxalactam resistance was most common in *P. aeruginosa.* Since 1982, amikacin resistance has increased for *K. pneumoniae* in all hospital categories.[3]

Mortality. Of the 54 NNIS hospitals, 50 (representing %50% of hospitalized patients with fatal nosocomial infections) assessed and reported the relationship of infection to death. These 50 hospitals reported mortality data on a total of 26,096 infections. Approximately 1% of infections were reported to have caused death, and 3.6% were reported to have contributed to death. Infections were more often reported to cause or contribute to death in the teaching hospitals.

Discussion

Nosocomial infections remain a significant cause of morbidity and mortality in hospitals in the United States. The National Nosocomial Infections Study is the only source of data collected prospectively on nosocomial infections from a group of U.S. hospitals. The nosocomial infections rate in NNIS hospitals during 1983 was 3.3 infections/hundred discharges, which is similar to the rate of infection reported for the 3-year period 1980-1982.[3] These data probably underestimate the true incidence of nosocomial infections in these hospitals; the Study on the Efficacy of Nosocomial Infection Control programs (SENIC Project) found that between 5% and 6% of hospitalized patients develop nosocomial infections.[1] Many factors contribute to this underestimating, including variability in the intensity of surveillance and availability of laboratory support. Despite the use of standard definitions of nosocomial infections by infection control personnel, the intensity of the surveillance conducted in these hospitals varies. In addition, the intensity of surveillance varies by service and pathogen. Furthermore, detection of viral infections depends more on the availability of virology laboratory support than on surveillance; therefore, hospitals without such support will not detect more viral infections.

Infection rates consistently increased from the non-teaching to the small teaching to the large teaching hospitals for all services and sites of infection, suggesting that this stratification of hospitals by hospital category effectively defines groups of patients who have different levels of risk for the development of nosocomial infections. This differential risk of infection is undoubtedly a by-product of severity of illness and the frequency of invasive diagnostic and therapeutic modalities. Data currently are not available specifically for intensive care units, but the rates of infection were highest on the surgery and medicine services, which have more high-risk patients, and lowest on the pediatrics and newborn services.

On the other hand, Valenti et al. have shown that viral nosocomial infections are more common in children than in adults.[5] In addition, Welliver et al. have shown that viruses account for approximately 14% of nosocomial infections in the pediatric population in a hospital where viral cultures are done routinely.[6] Since only a small proportion of NNIS hospitals have diagnostic virology laboratories, many viral infections probably go undetected. The failure to detect these infections may partially explain the lower nosocomial infection rates reported by NNIS hospitals on the pediatrics and newborn services. In addition, other factors, such as the short duration of stay by many pediatric patients and the frequent use of isolation precautions on the pediatric and newborn services, may reduce the incidence of nosocomial infections on these services.

Infection rates on different services and at different sites of infection within the three hospital categories varied little from those reported for 1982.[3] However, the increase in the primary bacteremia rates at non-teaching and large teaching hospitals identified during 1980-1982 continued through 1983, and a slight increase in the lower respiratory tract infection rate at non-teaching and large teaching hospitals emerged. Further study will be needed to identify the factors responsible for these increases.

Specimens for microbiologic testing were obtained from 90% of the patients reported to have nosocomial infections. For 85% of the nosocomial infections reported, an etiologic agent was identified; approximately 86% of these were aerobic bacteria. Fungi, parasites, and viruses were infrequently reported, reflecting in part the frequency with which these pathogens are looked for.

E. coli, S. aureus, enterococci, and *P. aeruginosa* were the four most common nosocomial pathogens. *E. coli* was the most frequently identified pathogen on the four adult services, reflecting the fact that this organism was the primary cause of urinary tract infections, which in turn were the most common type of infection on these services. *S. aureus* was the pathogen most frequently identified on the pediatrics and newborn services. Coagulase-negative staphylococci were the second most frequent cause of nosocomial infection on the pediatrics and newborn services and were an important cause of bacteremia on all services except gynecology. Further study will be required to assess the contribution of coagulase-negative staphylococci to the increasing rate of primary bacteremia, though recent studies suggest that the increasing use of long-line catheters may be responsible for this trend.[7]

Previous analyses of NNIS data have suggested that secondary bacteremia carries an increased risk of death.[3] Among the major sites of infection, cutaneous infections were most likely to result in secondary bacteremia, followed by lower respiratory, surgical wound, and urinary tract infections. Infections at sites other than these four major sites were, collectively, more frequently associated with secondary bacteremia. These include cardiovascular, arterial, intra-abdominal, and central nervous system infections. Because of the increased risk of death associated with secondary bacteremia, these infections should be a high priority for prevention and control.

Previous analyses have shown the incidence of methicillin-resistant *S. aureus* infections to be greatest at large teaching hospitals.[8] The 1983 NNIS data suggest that the incidence of methicillin-resistant *S. aureus* is now increasing in non-teaching and small teaching hospitals as well. Further study will be needed to discern the factors responsible for this increase.

Compared with 1980-1982, aminoglycoside resistance among *K. pneumoniae, S. marcescens,* and *P. aeruginosa* organisms also has increased in 1983 at non-teaching hospitals, and amikacin resistance has increased for all three organisms at the small teaching hospitals.[3] The frequency of resistance to the third-generation cephalosporins, however, did not vary consistently by hospital category. The number of *K. pneumoniae* and *S. marcescens* specimens tested for resistance to cefotaxime and moxalactam was very small, so data regarding cefotaxime and moxalactam resistance in these organisms should be interpreted cautiously. Since 1982, both cefotaxime and moxalactam resistance among *P. aeruginosa* isolates has increased at non-teaching and small teaching hospitals. At the large teaching hospitals moxalactam resistance among *P. aeruginosa* isolates has increased, but cefotaxime resistance has decreased.

This nationwide nosocomial infection surveillance system is expanding in four directions. First, despite the usefulness of the 3-category stratification of hospitals used in this report, an infection-risk index identifying patients with different levels of risk of nosocomial infection is needed to permit more meaningful comparisons between hospitals. Infection rates at different institutions could then be compared within levels of patient risk or standardized for differences of distribution of patient risk. Second, microcomputer software to support an integrated nosocomial infection information management system in each hospital is being developed to improve the quality and timeliness of information collected in NNIS. Third, data on antimicrobial usage are needed to permit an assessment of the impact of antimicrobial usage on patterns of resistance in nosocomial pathogens. Finally, additional hospitals will be included in the surveillance system to provide data from a more representative sample of all acute-care hospitals in the United States.

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AMA Looks at Peer Review Organizations

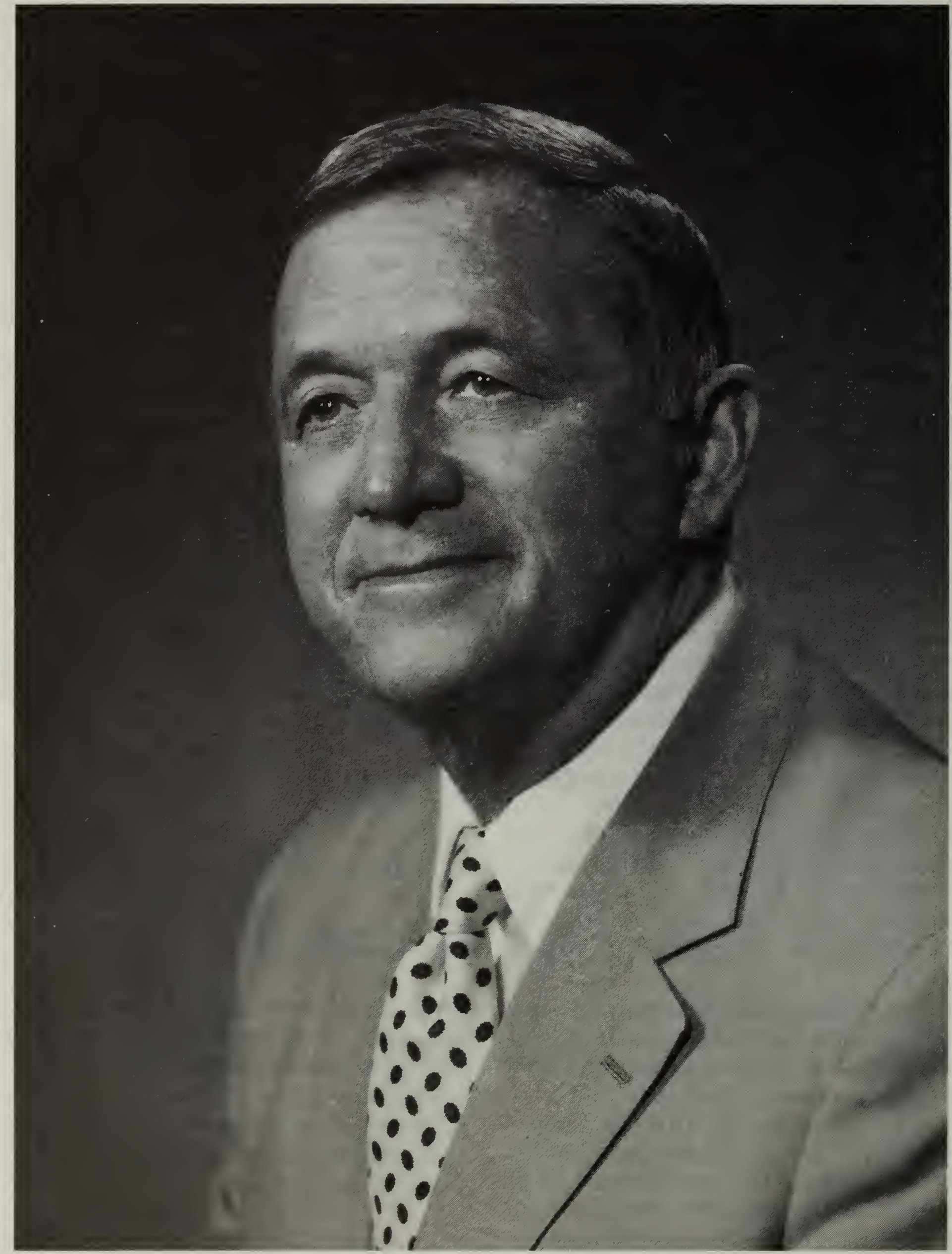
The American Medical Association announces an innovative new program to evaluate physicians' and hospitals' experiences with the Peer Review Organizations (PROs) set up to monitor the health care delivered to Medicare beneficiaries. Under the PRO program, both utilization and quality issues will be looked at by state level PROs under contract to the federal government. A percentage of all Medicare discharges will be reviewed with respect to a set of quality and utilization objectives contractually agreed to by each PRO with the Health Care Financing Administration (HCFA).

The AMA is interested in learning of individual physicians' and hospitals' experiences, both positive and negative, which they feel are attributable to the new peer review system. Areas of interest include: changes in length of stay, admission and discharge policies, preadmission certification procedures, utilization and quality review results, administrative relations between hospitals and physicians and the PROs, and the results of any PRO efforts to review patients other than Medicare beneficiaries.

Physicians and hospital medical staffs who would like to share this information with the AMA are encouraged to describe their experience(s) in a brief letter and direct it to:

AMA PRO Monitoring Project
Department of Health Care Financing & Organization
American Medical Association
Post Office Box 10947
Chicago, Illinois 60610

All sources of information provided will be kept confidential.



WILLIAM A. WHALEN, M.D.
President

WILLIAM A. WHALEN, M.D.

Born: New Britain, CT, July 1, 1925

Education:

1943—Graduate, New Britain High School, New Britain, CT
1949—A.B. Duke University, Durham, North Carolina
1953—Doctor of Medicine, Yale University, New Haven, CT
1953-1954—Surgical Intern, Yale-New Haven Hospital, New Haven, CT
1954-1957—Resident Physician, General Surgery, Yale-New Haven Hospital, New Haven, CT
1957—Resident Physician, Cardiovascular Surgery, Yale-New Haven Hospital, New Haven, CT
1958—Chief Resident Physician, Thoracic Surgery, Yale-New Haven Hospital, New Haven, CT
1958—Chief Resident Physician, General Surgery, Yale-New Haven Hospital, New Haven, CT

Military Service:

1944-1946—United States Navy Hospital Corps

Occupation:

1959-Present—Private practice, General, Thoracic, Vascular Surgery, Willimantic, CT

Hospital Appointments:

Staff Surgeon, General Thoracic and Vascular Surgery, Windham Community Memorial Hospital, Willimantic, CT
Chief of Staff—Windham Community Memorial Hospital, Willimantic, CT, 1982-1984

University Appointments:

Associate Clinical Professor, Surgery, Yale University, New Haven, CT

Activities:

1960—Diplomat, American Board of Surgery
1962—American College of Surgeons
1969—New England Surgical Society
1960—Connecticut Society of American Board Surgeons
1966-1968—Connecticut Society of American Board Surgeons, Secretary-Treasurer
1972—President, Connecticut Society of American Board Surgeons
1959—Windham County Medical Association
1974-1975—President, Windham County Medical Society
1962-1974—Member Professional Education Committee, Connecticut State Medical Society
1962-1966—Member Executive Committee, Cancer Coordinating Committee, Connecticut State Medical Society
1976-1982—Counciller, Windham County, Connecticut State Medical Society
1982—Vice-Chairman, Connecticut Statewide Medical Planning Committee, Connecticut State Medical Society
1978-1982—House of Delegates, American Medical Association
1982-1983—Vice-President, Connecticut State Medical Society
1983-1985—Present, Elect, Connecticut State Medical Society

Honors:

Edward H. Storer Award For Excellence in Surgical Teaching presented by Surgical Chief Residents, Yale Surgical Department, 1983

The President's Page

Quality of Care

The term QUALITY OF CARE is the most overused phrase in the realm of medical conversation today. It is rarely defined, yet each of us subconsciously or intuitively understands the meaning of the phrase and believes that our personal behavior patterns fulfill the definition of the term.

Basically, Quality of Care implies and demands, firstly, the *availability* of a physician who will render care in an *honest, dependable* and *accountable* manner, and secondly, of equal importance, one who guides the patient and the family through a medical or surgical experience as painlessly, realistically, and economically as possible. Theoretically this is the highest standard of care that can be rendered to a patient.

The major threat to the present standard of care is the over emphasis on the economics of care. As physicians, we support cutting waste but not the essential costs which are necessary for the preservation of a high standard of care. With the focus on decreasing costs, increased pressure is being placed on the maintenance of quality of care. The public must be educated on the possibility that the economics of care may affect *their* personal definition of quality of care.

The major participants in the reimbursement of health care, namely, the Government, Big Business, the Insurance Industry assume that in spite of the imposition of excessive regulations and restraints on the physician that quality of care will be maintained because of the basic dedication of the physician to do what is best for the patient!

Assuming present day trends continue, the critical breaking point will inevitably arrive where the physician can no longer render care according to his/her high standards. The key issue is what is the critical point at which the present day "regulatory overkill" will destroy the standard of care.

It is the responsibility of the Connecticut State Medical Society to define the precise point at which this occurs. This will require the cooperation of the entire membership. During the coming year, the public must be notified of our resolve to continue to cut waste but not at the expense of care. We must rededicate ourselves to do what is best for each individual patient, and that when our mutual concept of quality of care is breached that we will act together with our patients to restore the highest standard of care.

William A. Whalen, M.D.
President

Reflections on Medicine

What Policy?

ROBERT U. MASSEY, M.D.

At a recent conference devoted to the care of the aged the participants referred often to America's lack of a health care policy.

One hospital administrator disagreed; she said that the Medicare prospective payment system was the policy. The goal was to preserve the Medicare fund. A regulator said the policy was to "ratchet down" each year for about ten years, and by then we should have a system for rationing medical care. A physician argued that 11 per cent of the GNP was possibly not enough, given the quality of modern medicine and the aging of the population; we should not compare the medical care of the 1980s with that of the 1920s when the costs were less than four per cent of the GNP. Someone remarked that no one was paying enough attention to the economic value of better health and better medical care.

The objective of the conference had been to consider health care for the aged; some of the older members were getting impatient. They had been listening to data showing how much it cost to take care of them, but they wondered how money had come to define policy rather than the other way round. The physician had seemed closest to their point of view when he asked whether all the attention ought to rest upon the percentage of the GNP used to provide medical care.

One gentleman, old enough for Medicare, observed that money, in his view, should be considered but one of the means for effecting policy decisions once they had been made. Budgets themselves were not policy; he noted that the outward signs of our health policy, or lack of it, were an unbelievable babel of conflicting laws and regulations. He despaired of our finding a way out of the mishmash without some sort of coherent national philosophy. Special interest groups and their powerful influence on legislators, whose attention was fixed on the next election, made statesmanlike policy-making an almost unachievable ideal.

It is easy enough to look at health care systems in other industrial nations and contrast their apparently efficient workings with our disorderly way of doing things. Their organization and effectiveness, and sometimes lower costs, look better from a distance; close up we recognize that their ways mostly would not suit us; we see that they never would have evolved from our history.

We shall have to design our own, or let it develop untended out of our experience. It has not been impossible in the past for legislators to give expression to a policy which has already taken its form from the national will, but it may be far more difficult now. We are more divided in our philosophies, and the special interest people speaking in their shrill and often uncivil tongues are not likely to persuade the unconvinced, but are quite capable of paralyzing the work of civil society.

In the last century we built a public school system which was and remains the foundation of our democracy, and which, if generously sustained and faithfully managed, will assure our continued well being and freedom into the next century and beyond. Free public education arose as a clear expression of the public philosophy. We also have a system of medical education in the responsible hands of the faculties of 127 autonomous academic medical centers and their affiliated hospitals; it has come to be acknowledged world-wide as the best one going. Like our public schools it came into being as the expression of a public philosophy having to do with the values we placed upon health, physician education, and medical research.

Our public philosophy in matters relating to our health began to take shape in the 18th century Enlightenment, assumed spirit and substance with the humanitarian and scientific movements of the 19th century, and acquired faith and enthusiasm during the Progressive Era of this century. Not many years ago we affirmed that health care was one of our universal human rights. We have now only to write the essentials of the program, to agree generally upon the requirements, calculate the costs, and design an equitable means for financing. By no means a simple task, but then neither is tax reform. If it is to be done in our lifetime, the long debates must begin now in all seriousness, and take the high road of human need, not the low road of bottom line. The physicians and their patients have to seize the initiative from the "medical-industrial complex." The objective should be a health policy suited to our ideals, not just another scheme for raising capital and paying doctor and hospital bills.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Alcohol, Law and Public Policy: Current Controversies

JOSEPH M. HEALEY, J.D.

Efforts to reduce the suffering caused by the use or abuse of alcohol have attracted considerable attention during recent years. In New Jersey, the state Supreme Court held that a host who serves liquor to an adult social guest, knowing both that the guest is intoxicated and will be operating a motor vehicle, may be liable for injuries inflicted on a third party as a result of the negligent operation of a motor vehicle when this negligence is caused by the intoxication.[1] Under such circumstances, the potential liability of the host is expected to reinforce responsible behavior on the part of the guest. On a societal level, public health measures designed to reduce deaths and injuries caused by intoxicated drivers have led to the development of programs using "sobriety checkpoints" to deter individuals from driving while intoxicated and to detect those who persist in doing so. The use of these checkpoints raises important questions about the role of the state in promoting the public health, safety and well-being and the legally permissible means available to carry out this role. The courts of highest jurisdiction in New York[2] and in Arizona[3] have recently grappled with the balancings of the rights of society and the rights of the individual. These decisions provide insight into this important area of medicolegal controversy.

In both cases, the goal of the program was to reduce automobile accidents and to prevent suffering and death caused by those driving while impaired or while under the influence of alcohol. Each program involved the use of roadblocks or checkpoints to evaluate the drivers of automobiles for intoxication. In both programs, police officers acted pursuant to written protocols which described a limited basis for questioning the sobriety of a driver and for employing further screening tests. The checkpoints were positioned at prescreened locations and at times expected to yield the most effective results. The constitutionality of each program was challenged by a driver arrested as a result of the checkpoint system. At issue was the extent to which the checkpoints represented "unreasonable" seizures in violation of the Fourth Amendment of the United States Constitution.

Both decisions acknowledged that the use of the checkpoints was a seizure subject to review under the Fourth Amendment. Both identified the central question to be the seizure's reasonableness in light of the liberty rights of the individual and the public health and welfare concerns of society. Though each followed a slightly different path, both courts agreed on a three part conclusion: (1) that the state has a legitimate interest in protecting society from the harm done by intoxicated drivers; (2) that the checkpoint program represented an appropriate means to advance that interest; and (3) that the intrusion upon personal privacy imposed by the program was not so severe as to render the program unconstitutional. Neither concern about the potential abuse of the checkpoint system nor criticism of its cost-effectiveness convinced either court. In both cases, the use of the checkpoint program was affirmed and the convictions upheld.

These cases represent an important area of current interest dealing with problem drinkers. They involve the search for an appropriate balance between concern for the well-being of the intoxicated driver and of the potential victim. In both cases, there was a good deal of emphasis on the harm caused by intoxicated driver and by the legitimate interest of the state in curbing it. Through tight regulation of the discretion of the police, the potential for abuse is being minimized. The use of checkpoints in such a setting is likely to be viewed as one of the most important public health strategies dealing with the intoxicated driver.

REFERENCES

1. Kelly v Grinnell, 476 A2d 1219, NJ, 1984.
2. People v Scott, 63 NY2d518, 1984.
3. State v Superior Court 143 Ariz 45, 1984.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

MEDICOLEGAL BRIEFS: IS MEDICAL STAFF PEER REVIEW STATE ACTION?

State actions are exempt from federal antitrust enforcement. A physician whose clinical privileges at a private hospital were terminated, filed an antitrust suit against the hospital, its board of directors, the executive committee, the special ad hoc committee, and an independent medical audit firm. All were participants in the peer review process that resulted in the physician's loss of clinical privileges. The physician alleged that the defendants conspired together to restrain trade and had monopolized the market for orthopedic and neurological spinal surgical procedures in the community, thus violating the Sherman Act.

The Court of Appeals held that the peer review actions complained of by the physician were "state actions" and therefore exempt from the federal antitrust laws. The court held that to be exempt from the antitrust laws as "state actions," the conduct complained of must meet two standards. The conduct must be clearly articulated and affirmatively expressed as policy of the state. Secondly, it must be actively supervised by the State.

To establish that the conduct was clearly articulated and affirmatively expressed as state policy, the court noted that the statutes of the state required hospital medical staffs to review the quality and necessity of care provided to patients in the hospital. Furthermore, the statutes require hospitals to establish peer review committees to evaluate the qualification of health care providers in the hospital.

In considering whether the state actively supervised the peer review activities of medical staffs, the court pointed out that the state established both a medical licensing board and a hospital licensing council by statute. These agencies promulgate rules and regulations establishing standards for medical practice and the management of hospitals. The court noted that although the records and decisions of peer review committees are clothed with the statutory protection of confidentiality, the medical licensing board is required to review the records and decisions of peer review committees. Furthermore, the members of the peer review committees are granted statutory immunity from liability for their actions as members of the peer review committee.

Finally, the court observed that the statutes imposed on the peer review committee an obligation of providing any individual practitioner affected by peer review actions with a due process evidentiary hearing. Also, the court noted that any adversely affected individual physician had recourse to the state courts for judicial review of the peer review committees action if he or she were denied due process or if the decision was arbitrary or capricious.

In ruling against the physician the court said: "Common sense dictates that a cause of action under the Sherman Act is not created everytime...a physician, surgeon, or specialist has hospital staff privileges denied or revoked...we hold that the defendants' (peer review) actions are exempt from the federal antitrust laws under the doctrine of state action." (*Marrese v. Interqual, Inc.* U.S. Court of Appeals, Seventh Circuit, No. 83-1581, 1984).

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

PATIENTS EXPECT A STOOL EXAM

To the Editor: It is anticipated that 123,000 new cases of carcinoma of the colon will be detected in the United States during 1985. The five year survival rate can be clearly associated with the extent of disease detected at the time of discovery (Duke's classification).

According to Dworkin and Winawer, "results of screening men and women, mostly of average risk, over age 40 with fecal occult blood test reveal a positive rate of 1% to 4% with a predicted value of neoplasia 44% to 50%." "The fecal occult blood test can detect from 30 to 75% of colonic adenomas, depending on their rate of bleeding, size, location, and the technique used in the occult blood test." [1]

Blood testing slides are readily available and convenient to use. Our patient population is being educated to expect a digital rectal examination with "chemical testing" for blood.

Stool examinations for blood should be a standard part of any complete exam on a patient 40 years old or older. This does not replace sigmoidoscopy but rather is complementary to it.

Robert E. White, M.D.

Colorectal Health Check Committee
Connecticut Division, American Cancer Society

REFERENCE

1. Dworkin BM, Winawer SJ: Neoplastic Colonic Polyps: A Review. Current Concepts in Gastroenterology, 10:3-15, 1985.

MORE ON COMMUNICATION SKILLS

To the Editor: In the April issue of *Connecticut Medicine* Dr. Ragusa reminds us that our communication skills need improvement. His insight merits a comment.

I think that our communication skills will improve only when patients and their insurance companies are aware of the value and difficulty of communicating.

Talking to patients can be one of the most difficult aspects of a physician's practice particularly those in Primary Care upon whom the brunt of "talking to patients" falls. Talking means reassuring, explaining, exhorting, absorbing, and understanding. Talking can be difficult and frustrating. It can also be very satisfying. It is always time consuming and can be very exhausting to the doctor.

Increasingly, patients demand and need this so-called cognitive aspect of medical care. The intracacies of our technology, the specter of malpractice litigation, and the anxieties of our uptight society make good communication skills a high priority. However, patients and insurance companies are unaware of the *value and difficulty* of this skill. They take it for granted.

The point is that until physicians, particularly Primary Care physicians, receive adequate compensation for this skill, it will probably not be much improved upon. Good communication skills are neither negligible nor unworthy of respect and are every bit as important and as difficult as the skill required to remove a gall bladder or perform a cardiac catheterization.

Edward J. Volpintesta, M.D.

Bethel, CT

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Editorial

Physicians Against Drunk Driving

There is a scourge in our land—the intoxicated driver.

That individual while driving under the influence (DWI) of alcohol is responsible for incalculable suffering at a yearly cost to our society of 17,847 highway deaths, 750,000 injuries and 24 billion dollars. Yet, as Brandt et al point out in the article "Drunken Injured Drivers: Are they "getting away with murder"? on page 377 of this issue of Connecticut Medicine the culprit of the carnage on our highways, the drunken injured driver, is seldom cited for DWI and even more rarely convicted. Of 30 drivers studied, 29 (96.7%) had blood alcohol concentrations greater than that legally stipulated as alcohol intoxication and more than two-thirds of the drivers had double that concentration. Yet only two (6.9%) were cited for DWI and only one (3.4%) was convicted.

Almost daily in our media there is evidence of the mounting nation-wide campaign to rid our streets of the intoxicated driver who has caused so much heart-break, so much devastation in his wake. But powerful forces, some quite bizarre, tend to protect the rights of the drunk driver and a weak state law permits him to get off with minimal punishment even after causing considerable injury and property damage.

Rights protected under the Fourth and Fifth Constitutional Amendments provide for the driver's written agreement to allow the testing of blood, breath or urine so the objective evidence of alcohol intoxication is hard to get and harder to introduce into court. Strangely, head injury, which occurs so frequently in drunken driving, paradoxically protects the "drunk as a skunk" driver from citation for DWI because courts have disallowed prosecution due to the confusion of side-effects between alcohol and head injury. The state law, though implying guilt by refusal of alcohol testing and potentially serious consequences including fines and jail, does not permit such refusal into evidence and provides accelerated rehabilitation that is nothing but a "slap on the wrist."

Although personal rights must always be of paramount concern, the rights of society are in the balance as well. The drunken driver is "getting away with murder" at society's expense.

The families of DWI victims, 11 million in the last decade, are devastated by their losses and angry at witnessing the inactions of the current judicial system. The drunken drivers are aware of the "free ride" the law will give them the first time.

There needs to be an end to the undeclared one-sided civil war in this country that pits drunken drivers in swerving cars against innocent victims, often themselves.

However, legislative bottlenecks controlled in committee by what may be self interested parties, obstruct passage of major deterrent bills which increase first offense penalties for conviction of drunk driving, set a "per se" standard of blood alcohol concentration at 100 mg% (in place in many other states) and allow introduction of hospital blood alcohol levels into evidence in court.

Emergency Medical Services Systems should be certain that responders and emergency physicians and nurses document fully the observations which indicate alcohol intoxication. There may be a new era in which emergency physicians may be enlisted in the battle against DWI by court appearances, perhaps to testify against their own alcohol intoxicated patients.

The Connecticut State Medical Society and The American College of Emergency Physicians are already strongly against DWI. The issue is serious, but largely preventable.

There is a meaningful way each of us can play a part—write Representative Edith Prague and our own legislators supporting Bill 5158 to increase first conviction penalties for DWI. Supporting recommendations to strengthen state law is a clear signal to the Public, drivers and victims alike, that DWI must be dealt with firmly and justly.

Allan A. Brandt, M.D.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself reponsible for statements made by any contributor.

IN MEMORIAM

BACKHUS, LOUIS C., Syracuse University College of Medicine, 1933. Dr. Backhus was an obstetrician and gynecologist in the New Haven County area since 1935. He was past secretary of the Connecticut State Medical Society, a past president of the Waterbury Medical Association and past president and executive board member of the New Haven County Medical Society. He also served on the staff of St. Mary's Hospital. Dr. Backhus was a member of the American Medical Association; died March 25, 1985 at the age of 78.

BEEBE, JOHN T., Columbia Physicians & Surgeons College, 1938. Dr. Beebe was an internist in the Hartford County area since 1942. He served on the honorary staff of Hartford Hospital. Dr. Beebe was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 18, 1985 at the age of 76.

CAMPBELL, CARLETON, Long Island College Hospital, 1925. Dr. Campbell was a general surgeon in the Fairfield County area since 1951. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died November 30, 1984 at the age of 89.

CHARTIER, GERARD M., Boston University School of Medicine, 1933. Dr. Chartier was a general practitioner and general surgeon in the Windham County area since 1933. He was on the staff of the Day Kimball Hospital, and in 1948 he opened the Danielson Clinic in partnership with other doctors. Dr. Chartier became chief of staff at the hospital in 1958 serving in that capacity for 14 years. He retired in 1981 after 47 years of medical practice. Dr. Chartier was past president of the Windham County Medical Association, and was a member of the Connecticut State Medical Society and the American Medical Association; died March 10, 1985 at the age of 76.

deFOREST, GIDEON K., Yale University School of Medicine, 1932. Dr. deForest was an internist in the New Haven County area since 1942. He was a staff member of Yale-New Haven Hospital and a consulting physician at the V.A. Hospital in West Haven. Dr. deForest was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 11, 1985 at the age of 78.

FOSTER, JOHN H., University of Pennsylvania College of Medicine, 1917. Dr. Foster was an internist in the New Haven County area since 1927, retiring in 1972. After serving in the U.S. Army Medical Corps in World War I, he returned to China, representing Yale University at its medical school in Changsha. He served as president of Waterbury Hospital. Dr. Foster was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 2, 1985 at the age of 93.

HARDENBERGH, DANIEL B., Harvard Medical School, 1934. Dr. Hardenbergh was an internist in the Fairfield County area since 1936. He served as Chief of Medical Services, Chief of the Department of Medicine, Director of the Out-Patient Department, and Director of the Arthritis Clinic at Bridgeport Hospital. Dr. Hardenberg was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 25, 1985 at the age of 75.

INKSTER, JAMES H., Cornell University School of Medicine, 1930. Dr. Inkster was a general practitioner in the Fairfield County area since 1943. He served in the U.S. Army during World War I. Dr. Inkster was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 25, 1985 at the age of 85.

KATZ, DEWEY, University of Vermont, 1925. Dr. Katz was an ophthalmologist in the Hartford County area since 1937. He served as a consulting physician at the New Britain General Hospital. Dr. Katz was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 4, 1985 at the age of 85.

PIERSON, LOUIS A., Tufts Medical School, 1927. Dr. Pierson was a internist in the New Haven County area since 1930. He served as Chief of Medicine at the Meriden-Wallingford Hospital. Dr. Pierson was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died January 27, 1985 at the age of 82.

ROSENBERG, MARC D., New York University Medical School, 1956. Dr. Rosenberg was an anesthesiologist in the New Haven County area since 1961. He was attending at Yale-New Haven Hospital. Dr. Rosenberg was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died February 27, 1985 at the age of 54.

SIMONDS, JOHN R., University of Vermont, 1938. Dr. Simonds was a general practitioner in the Litchfield County area since 1946. He served with the Army Medical Corps in the Pacific during World War II and was past president of the New Milford Hospital Staff. Dr. Simonds was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died March 6, 1985 at the age of 71.

TOBI, LOUISE G., Utrecht, 1931. Dr. Tobi was a general practitioner in the Windham County area since 1952. She served on the staff of the Windham County Memorial Hospital, retiring in 1973. She was a member of the Windham County Medical Association and the Connecticut State Medical Society; died recently at the age of 83.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Opportunity available in our 220-bed community hospital with an active prehospital care program for a full time emergency medicine trained or practice tract prepared physician. Our six full time physician staffed department has a volume of 28,000 visits annually. Excellent benefits and competitive salary are offered. Please send CV to Patricia C. Kuszler, M.D., Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT 06450.

Farmington Valley, CT. Full time emergency physician needed immediately for walk-in treatment center. Opportunity for full partnership. Write CSMS, c/o EM/JR.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

FAMILY PRACTICE

Board certified or eligible residency trained family physician wanted to associate with same in a growing town of 20,000 in the foothills of the Connecticut Berkshires. Established, growing practice—salaried first year; full partnership in second year. No OB. Send CV to P. Anderson, M.D., One Old Park Lane, New Milford, CT 06776.

Family physician to join board certified residency trained family practitioner in a growing, two office practice in Guilford or Essex on the shoreline. Beautiful area; enjoyable life style; excellent schools. Great opportunity for professional and personal satisfaction. Will consider part-time. Reply to, Alan Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

INSTITUTIONAL MEDICINE

JCAH-Accredited 350-bed State Hospital seeks the services of a board eligible physician with experience or interest in Respiratory Therapy and a willingness to participate in limited administrative functions. Work week of five days, 35 hours with liberal State fringe benefits. Send C.V. to R.J. Cavalieri, M.D., Chief of Medicine, Veterans Home and Hospital, 287 West St., Rocky Hill, CT 06067.

Walk-In Medical Services is seeking full and part time physicians to work in a convenience medical facility in Orange, CT. FAM. PRAC/IM preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Internist—University-based HMO seeks inquiries and applications for staff positions. Competitive salary and benefits programs. Contact, Medical Director, Yale University Health Services, 17 Hillhouse Ave., New Haven, CT 06520 (Tel. 203-436-8433).

PEDIATRICS

BE/BC pediatrician wanted to join practice of three pediatricians and PNP in Middletown. Excellent salary and fringe benefits leading to full association. 350 bed community hospital with Level II nursery and F.P. residency program Please send resume to Middlesex Pediatric Assoc., P.C., 80 South Main St., Middletown, CT 06457.

PRACTICE FOR SALE

General, active surgical practice for sale in southern Connecticut. Medium-sized city. Well equipped office including fully equipped minor surgical suite. Available July 1, 1985. Reply to CSMS, c/o SALE/BB.

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

PRIMARY CARE

Primary Care Physicians, BC/BE, needed to join expanding Walk-In Medical Center Group in central Connecticut. Full or part-time positions available. Compensation package includes competitive salary, malpractice insurance, and profit sharing opportunity. Stimulating work experience in a comfortable setting with flexible scheduling. Send C.V. to: PhysicianCare, 28 Main Street, East Hartford, Ct., 06118, or call (203) 569-8644.

Physicians—Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

PSYCHIATRY

Consulting psychiatrist for community-oriented psychosocial rehabilitation agency. Licensed required. Psychiatrists needed to provide three hours, every other week of consultation services at a facility serving the greater Norwich area. Clientele consists of poor, chronically mentally ill adults. Send inquiries to David Burnett, Executive Director, Reliance House, Inc., 132 Broadway, Norwich, CT 06360.

Child Psychiatrist needed for full to part-time, in greater Hartford area, to join a well established office and hospital practice. Reply to CSMS, PSY/MN.

RADIOLOGY

Part-time radiologist, board eligible or certified for private office practice in greater Hartford area. Please send CV to CSMS, RAD/CC.

Radiologist wanted part-time for general diagnostic radiology in private office practice in Waterbury area. All replies confidential. Write CSMS c/o RAD/AA.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

Immediately available. Age 31. AB elig. MD, G.S. Medical College; Int., Flushing Hospital of Medical Center, NY; Res., Albert-Einstein College of Medicine, NY; Fellowship, Maimonides Medical Center, NY. Prefers solo, group or associate type practice. Write, Vasant Chheda, M.D., 950 49th St., Apt. 8K, Brooklyn, NY 11219.

July '85. Age 39. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Bangalore Medical College, India; Res., Cheettenham General Hospital, Dryburn Hospital and Birmingham Accident Hospital, U.K.; Fellowship, Maimonides Medical Center, Brooklyn, NY. Interested in OB Anesthesia, Pediatric Anesthesia and General Surgery with a group, associate or institutional type practice. Write, Yellagondahalli Janardhan, M.D., Apt. 108, 34 Minebrook Rd., Edison, NY 08820.

Aug. '85. Age 33. Presently in practice. FLEX. AB elig. MD, Far Eastern University, Philippines; Int. and Res., State University of NY, Downstate Medical Center; Fellowship, State University of NY (OB and PED Anesthesia). Prefers solo or group type practice. Write, Frederick D. Moser, M.D., 143-47 Barclay Ave., Flushing, NY 11355.

EMERGENCY MEDICINE/FAMILY PRACTICE

Cromwell, Connecticut seeks high quality physician for Ambulatory Care, Freestanding Walk-in Medical Center. Position available for full and part-time. Emergency Medicine and or Family Practice physician desired with strong communication and marketing management skills. Reply with C.V. and cover letter stating availability and salary requirements to: Gail Brown, Medical Center Consultants, 2279 Grand Island Blvd., Grand Island, New York, 14072.

FAMILY PRACTICE

July '85. Age 59. Licensed in Connecticut. Presently in practice. AB cert. MD, University of Heidelberg Medical School; Int., Mary Immaculate Hospital, Jamaica, NY; Res., St. Catherine's Hospital, Brooklyn, NY; Fellowship, New York University, NY (one yr. course). Prefers institutional type practice. Write CSMS, HJS/FP.

Aug. '85. Age 34. Nat'l bds. AB elig. MD, University of Colorado, Denver, CO; Int. and Res., Kaiser Permanente, Fontana, CA. Prefers group type practice in a medium-sized community. Write, Barry R. Hansen, M.D., 919 Emerson Pl., Clarement, CA 91711.

July '85. Age 38. Licensed in Connecticut. AB elig. MD, T.N. Medical College, Bombay, India; Int. and Res., Medical Center of Central Georgia, Macon, GA. Interested in group, associate, institutional or HMO in a community of 20,000-30,000 within 30-40 miles of big metropolis for CME and referral. Write, Kamrudin K. Mithani, M.D., 3540D Lake Terrace Pl., Macon, GA 31204.

GENERAL PRACTICE

March '85. Age 38. Licensed in Connecticut. MD, S.M.S. Medical College, Jaipur, India; Int., Doctor's Hospital, Toronto, Canada; Res., St. Joseph's Hospital, Toronto; University of Toronto (Psychiatry). Prefers solo, group, associate or industrial type practice. Write, Nalini Menon Pathiyal, M.D., Apt. A-2, 9 Concord St., West Hartford, CT 06119.

INTERNAL MEDICINE

GASTROENTEROLOGY. July '85. Age 30. Nat'l bds. AB Cert. MD, NY University; Int. and Res., Downstate Medical Center, King County Hospital; Fellowship, NY Medical College. Desires solo, group or associate type practice. Write, CSMS, c/o MCB/IM.

Immediately available. Age 36. Licensed in Connecticut. Nat'l bds. AB Cert. MD, Universidad Autonoma de Guadalajara; Int. and Res., Elmhurst City Hospital. Interested in private practice in a small-sized community but will consider group or associate also. Write, Gary Bykoff, M.D., 32-42 89th St., Jackson Heights, NY 11369.

Aug. '85. Age 28. AB elig. MD, Mysore Medical College; Int. and Res., Grant Hospital of Chicago. Prefers group, institutional or industrial type practice in a large-sized community. Write, Benu Chatterjee, M.D., #459, 535 W. Briar, Chicago, IL 60657.

PRIMARY CARE. April '86. Age 32. FLEX. AB elig. MD, University of Rome, Int., Long Island College Hospital; Res., Illinois Masonic Medical Center. Desires group or associate type practie in a medium to large-sized community. Write, Eli R. Goldner, M.D., 2841 W. Rosemont, Chicago, IL 60659.

OBSTETRICS AND GYNECOLOGY

April '85. Age 30. Presently in practice. AB elig. MD, NY Medical College; Int. and Res., NY University/Bellevue Medical Center. Primarily interested in a group practice in a medium-sized community. Write, Andrew R. Herzog, M.D., 229 Haven Rd., Franklin Lakes, NJ 07417.

PEDIATRICS

PEDIATRIC PULMONARY. Sept. '85. Age 36. Presently in a clinical academic position. Nat'l bds. AB cert. (PED); AB elig. (PED. PUL). MD, Jefferson Medical College; Int., Pensacola Educational Program; Res., Scared Heart Children's Hospital, Pensacola, FL; Fellowship, University of Florida. Prefers group practice with at least two to three other Pediatricians. Teaching responsibilities welcome. Write, John S. Liggett, Jr., M.D., 7306 Hollyoak Drive, Tyler, TX 75703.

RADIOLOGY

NUCLEAR MEDICINE. July '85. Age 34. Nat'l bds. AB elig. MD, Albert Einstein College of Medicine, NY; Int., Bronx Municipal Hospital Center, NY; Res., Mallinckrodt Institute of Radiology, St. Louis, MO. Prefers group, associate or institutional type practice in a large-sized community. Write, William Ganz, M.D., 7476 Ahern Court, University City, MO. 63110.

DIAGNOSTIC. March '85. Age 33. Presently in practice. Nat'l bds. AB elig. MD, SUNY Buffalo School of Medicine; Int., University of Wisconsin Hospitals, Madison, WI; Res., Baystate Medical Center, Springfield, MA. Is flexible in practice consideration and wishes to practice in a small to medium-sized community. Write, CSMS, c/o LI/RAD.

July '85. Age 30. Presently in practice. Nat'l bds. AB elig. MD, SUNY Downstate, Brooklyn, NY; Res., Long Island College Hospital, Brooklyn, NY; Int., Nassau County Medical Center, NY; Fellowship, St. Louis University Medical Center, St. Louis, MO. Prefers general X-Ray with emphasis on CT/Ultrasound with a group, associate, institutional or industrial practice in a large-sized community. Write, Richard S. Steinberg, M.D., 3701 Lindell Blvd., Apt. 427, St. Louis, MO 63108.

SURGERY

GENERAL/VASCULAR. Immediately available. Age 39. FLEX. AB elig. M.B., Ain Shams University, Cairo, Egypt; Int. and Res., Mount Vernon Hospital, Mount Vernon, NY; Fellowship, Texas Heart Institute, Houston, TX and Baylor College of Medicine, Houston. Prefers group or associate type practice in a medium-sized community. Write, Wagih R. Mando, M.D., 7107 Hillcroft ffl404, Houston, TX 77081.

GENERAL. July '85. Age 30. Nat'l bds. AB elig. MD, St. Louis University School of Medicine; Int. and Res., St. Louis University Group Hospitals. Prefers group or associate type practice in a medium to large-sized community. Write Dan S. Reiner, M.D., 7028 Waterman Ave., St. Louis, MO 63130.

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Special Issue

St. Vincent's Medical Center: Michael A. Dean, M.D., Guest Editor

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Connecticut Tumor Registry, The First 50 Years: Jack W. Cole, M.D., Guest Editor

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A History of St. Vincent's Medical Center

St. Vincent's Medical Center became a reality because of the vision of a Catholic priest in Bridgeport, the encouragement of local physicians, and the commitment of the Daughters of Charity of St. Vincent de Paul, the largest order of religious women in the world and the sponsors of the Medical Center.

The hospital was incorporated under the state laws of Connecticut on May 19, 1903, and within two years the modern structure was completed for the grand sum of $250,000. The first patient was admitted on June 28, 1905, by Dr. William O'Hara, a physician who had worked diligently to help make the new hospital a reality. The first surgery took place on July 3rd of that year. It was for empyema. Three surgical procedures took place that same day, thereby beginning a long and proud tradition of surgical excellence at St. Vincent's.

The 75-bed hospital consisted of three floors and a roof garden. The Sister Administrator realized that more trained hands would be needed to assist the Medical Staff so she opened a School of Nursing in 1905 which immediately enrolled three men and nine women to begin a history of educational commitment. St. Vincent's is one of five Connecticut hospitals to have retained its nursing program to the present day.

The hospital's first Medical Staff consisted of 24 doctors with Dr. O'Hara serving as Chief Physician Representative. The number of doctors and patients grew consistently through the years. The community donated monies to help the hospital grow and no one was turned away from the services offered at St. Vincent's.

Construction of a fourth floor at St. Vincent's took place in 1913 with a nurses' home following in 1915 and a separate medical annex was built in 1918. During the 1930's a major addition would increase the hospital's capacity to 325 beds, thereby making St. Vincent's one of the largest hospitals in the state.

With the help of modern diagnostic and medical equipment, physicians at St. Vincent's were able to successfully complete a number of life saving surgeries which only a few years earlier would have been impossible. Names like Curley, Banks and McQueeney stood out as physicians whose practices grew dramatically in this era of new technology.

It was early in the history of St. Vincent's that physicians on the staff recommended the creation of a Medical Education program. With the cooperation of staff physicians, the hospital negotiated affiliations first with the New York University Medical School and with the Yale University Medical School to teach programs in Surgery and Medicine, with OB/GYN, Pathology and Radiology to follow. Graduates from these programs went on to practice not only in the Bridgeport area, but throughout the country. Many department chairman and chiefs of divisions at Connecticut hospitals are graduates of the St. Vincent's program.

Over 60 Residents and Fellows are currently able to pursue training opportunities in cardiology, respiratory medicine and other subspecialty fields. Today, St. Vincent's is among the 300 major affiliated teaching hospitals in the United States.

Training at St. Vincent's has not been limited to physicians and nurses. In 1954, the hospital opened its first training program for x-ray technicians. Currently, there are programs in Medical Technology, Respiratory Therapy, Ultrasound Technology, Nuclear Medicine to train technical personnel for hospitals as well as private offices.

The 1960's ushered in an era of dynamic change at St. Vincent's. In 1906 there were only a handful of admissions annually while in 1963 St. Vincent's had become the fifth largest hospital in Connecticut. By 1964 a climate for major change was ushered into St. Vincent's. An announcement to build a new hospital was made by Administration. The site was to be in Fairfield and most rooms were planned to accommodate one patient, something quite unusual at the time.

In 1970, a new direction in construction plans was announced. The hospital would be built, but not in Fairfield as originally planned. As a result of unexpected costs and concern about access to the hospital by the elderly, it was decided to construct the new facility behind the original building in Bridgeport. The Fairfield site was sold to General Electric as the location for its world headquarters.

Helped by generous donations from the community, plans for the new building were transformed from renderings to the first stages of construction. The new structure would be over 440,000 square feet, nearly twice the size of the old hospital. It would accommodate nearly 400 beds and include a space age matrix of new technology to help doctors care for their patients. It was to be ten stories high, a spectacle of glass and concrete with numerous amenities to make patients' stays more comfortable. Most hospitals added wings, additions or floors as they grew, but St. Vincent's was to be one of the very few hospitals in the United States to completely replace its facilities.

Approximately $41,000,000 would be spent on the project, and the day it was completed, the architects reported that replacement costs would require at least $65,000,000. Today, the same building would require at least $110,000,000 in capital and project costs, making the original expenditures a bargain by comparison.

The name of the hospital was changed to St. Vincent's Medical Center, reflecting the comprehensive range of services now available to patients. Dedication ceremonies welcomed the public to the new facility and on April 17, 1976, a highly complex transfer of 209 patients from the original building to the Medical Center was successfully completed. Shortly thereafter, the old building was demolished so that space could be used for badly needed parking accommodations.

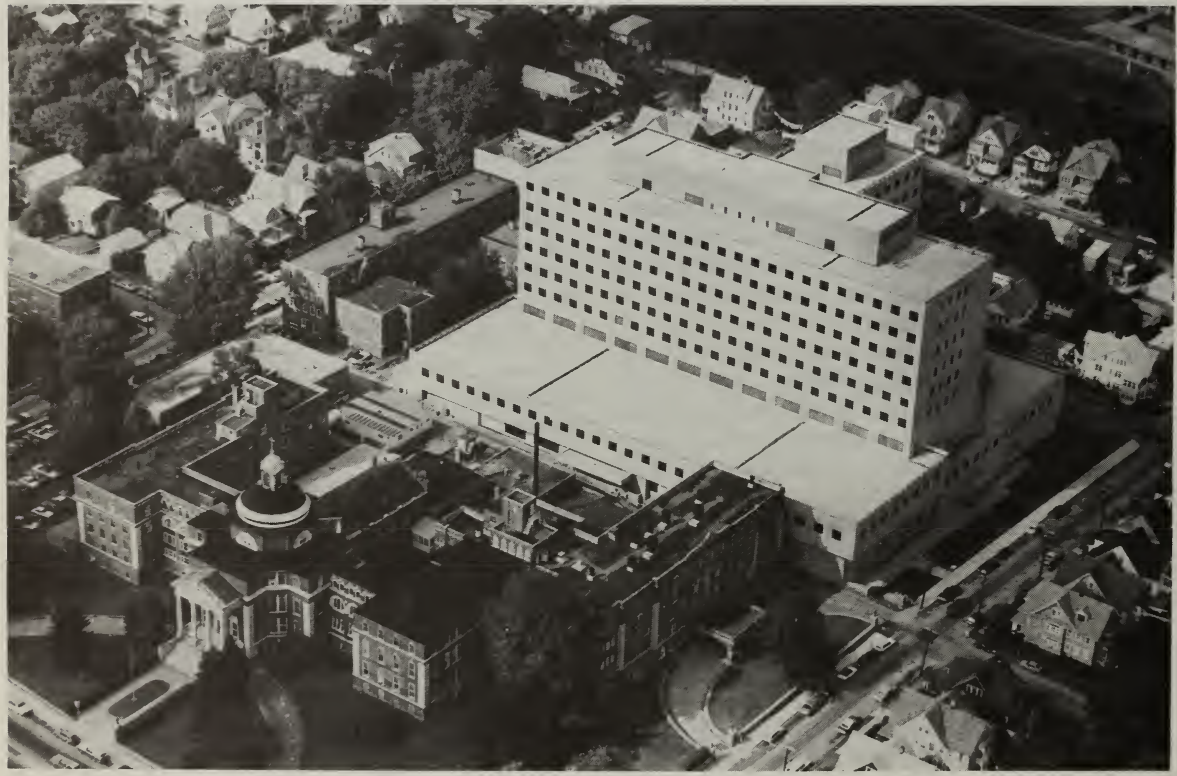
In the years following the opening of St. Vincent's Medical Center, energies were turned to program development. As one of Connecticut's first hospitals to utilize full body CT scanning, St. Vincent's developed a pacesetter department of diagnostic radiology. A reorganized and energized open heart program enabled St. Vincent's to provide refined services in this specialty to much of Southern Connecticut. This program had been designated as the regional open heart center for Fairfield County by the area Health Systems Agency. Utilizing a tri-partite approach of radiation therapy, surgery and oncology and the area's first dedicated cancer unit, St. Vincent's physicians have been able to do more than ever before to help the cancer patient.

In recent years emphasis on ambulatory surgery aided by a newly designed and expanded Short Stay Center has resulted in over 36% of all surgeries being done on a same-day basis by surgeons at St. Vincent's. Expanded programs in cardiology, physical therapy, and neurosciences were typical of the growth experienced in the last few years. Today, a renovated Emergency Department with express line care and a new Psychiatric Day Care Center are but a few of the new trends at St. Vincent's.

Over 250 attending physicians now use St. Vincent's as their hospital of choice. Over 60 Residents are completing their training in a medical education program which has prepared nearly 85 physicians for practice in the Bridgeport area alone.

Those who dreamed of building a new hospital in Bridgeport at the turn of the century would not recognize the modern facility of today, but they would be proud of the traditions, legacy and accomplishments which are part of the proud history of this institution.

Ronald J. Bianchi
Vice President,
St. Vincent's Medical Center



St. Vincent's Medical Center (background)—as seen in 1976—one of the few hospitals in the country to replace original buildings. The original building (foreground) has since been demolished to make way for parking.

Diagnostic Radiology in Vascular Disease of the Aged

ROBERT D. RUSSO, M.D., ROBERT D. RUSSO, JR., M.D., DAVID I. ROBBINS M.D., NORMAN R. VINCENT, M.D., SHASHI CHADDHA, M.D., GUY E. TORSTENSON, M.D., AND ORTWIN F. RUSCH, M.D.

Vascular disease ranks number one in diseases of the elderly. The recognition of symptomatology of vascular disease needs definitive confirmation of the location, extent and need of intervention or correction of the various vascular lesions. This can be accomplished by the various diagnostic and therapeutic imaging procedures now available in Radiology. Within recent years sophisticated imaging modalities such as cerebral, peripheral and digital subtraction arteriography, ultrasound, echocardiography including 2-D Doppler techniques, CT scanning, nuclear medicine studies and the promising new modality of Magnetic Resonance Imaging (MRI) appear to be boundless in their capabilities to define cardiac and vascular abnormalities. The authors of this article have reviewed the many modalities presently available in the modern active general hospital setting which can alleviate considerable suffering and disease in a significant number of patients.

Peripheral Vascular Disease

Peripheral lower extremity arteriosclerotic occlusive disease is a common problem in the elderly, particularly in heavy smokers and diabetics. Aorto-femoral arteriography is the definitive examination to assess the extent of arterial vascular disease of the legs. When the femoral pulses are adequate, this study is performed using a Seldinger technique through the femoral artery at the groin of the less affected leg. If the better femoral pulse is on the affected side, then that side is used for the study. Since most patients have bilateral disease, both sides are studied by advancing a catheter from the groin into the abdominal aorta. Contrast media is then injected into the abdominal aorta and aortic bifurcation. Serial radiographs are obtained from the pelvis to the ankle by means of a pre-programmable movable angiographic table. The patient often experiences a sensation of heat and slight discomfort during the passage of the contrast down the legs, which is due to the hypertonicity of the contrast material.

If the circulation of only one leg needs to be studied, then the procedure can be performed either through the arterial puncture needle itself or through a short catheter that is placed into the femoral or iliac artery on the affected side. Visualization of the vessels is then often better than when injecting from the abdominal aorta. When both femoral pulses are very weak or absent, a left axillary arterial approach is used. The catheter is advanced into the aortic arch from the left subclavian artery, and then manipulated down the descending aorta.

Once the extent of the disease is outlined by arteriography, a therapeutic decision is made as to the most appropriate treatment for that patient. Although the majority of patients with occlusive disease need bypass surgery, angioplasty can also be a viable alternative or adjunct to surgery in selective patients with non-occlusive stenosis.

ROBERT D. RUSSO, M.D., Chairman, Department of Radiology; ROBERT D. RUSSO, JR., M.D., Medical Director, CT Scan Division; DAVID I. ROBBINS, M.D., Medical Director, Ultrasound Division; NORMAN R. VINCENT, M.D., Medical Director, Nuclear Medicine Division; SHASHI CHADDHA, M.D., Neuroradiologist; GUY E. TORSTENSON, M.D., Diagnostic Radiologist; ORTWIN F. RUSCH, M.D., Diagnostic Radiologist; All are attending radiologists in the Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT.

The lesions most amenable to angioplasty are stenoses in the iliac, common femoral or superficial femoral arteries. The angioplasty technique used today was devised by Gruntzig and uses a special catheter. The Gruntzig catheter has a circumferential elongated balloon attached near the distal end which can be inflated from the catheter hub. The balloon is inflated for about thirty seconds after it has been placed at the stenosis. This compresses the atheromatous plaque back into the wall of the vessel, opening the stenotic segment. Long term results are very favorable in most patients. Recurrent stenosis occasionally occurs, at which time either bypass surgery or a second angioplasty procedure can be performed. Angioplasty does not require anesthesia, is performed in the angioplasty suite, and usually takes only one or two hours. Follow-up low-dose Persantine or aspirin therapy is usually instituted for a variable time period after the procedure.

CT Scanning in Vascular Disease

In the field of computerized tomography with its universal applications, atherosclerotic cardiovascular disease can be considered in multiple applications. Peripherally, the studies are called for in the most acute states. Rapid and accurate diagnosis of ruptured or dissecting aneurysms can be obtained within a half-hour's time. With the administration of contrast agent, surgically necessary information such as renal function and ureteral involvement can be gathered at the same time. Since speedy data acquisition is imperative, one scan series can provide the information quickly.

CT scanning is limited by spatial resolution when the internal structure of a vessel is needed. For example, when intimal flaps are to be considered, the entrance or exit points for long dissections must be delineated. It should be appreciated, however, that CT scanning can provide valuable information about false channels and dissections with the administration of contrast, as contrast clearly identifies the vascular space.

Measurements with CT scanning are accurate to millimeter distances; grading of an abdominal aortic aneurysm's size and, therefore, its prognosis can be estimated. Interestingly, atherosclerotic peripheral aneurysms are not all of the same configuration, as some have tremendous clot formation within their walls and little true channel, whereas others have thin-shelled adventitial layers, no clot, and very wide true lumen channels. Again, this data helps enormously when planning timeliness of operation, graft size and other hemodynamically significant problems. One of the largest areas of interest in CT scanning for peripheral atherosclerotic disease is in post-operative patients. CT scanning is the best non-invasive imaging modality to study the post-operative complications of cardiovascular grafting. Such lesions as graft infections, pseudo-aneurysms, seromas and occlusions can be identified by scanning without the risks of catheterization of graft sites.

The procedure itself is quite simple, as there is minimal preparation and patient discomfort. The patient is NPO for four hours before the procedure, given oral and intravenous contrast, and told to lie on the examination couch which passes through the x-ray gantry. Reconstructed images are obtained quickly and decisions can usually be made within the half hour of the start of the examination. In more routine studies, examination of BUN and creatinine values are recommended to gauge renal function before contrast is given.

It is, therefore, recommended that CT scanning in peripheral atherosclerotic disease be used in acute cases of suspected abdominal aortic aneurysms to rule out hemorrhage and/or dissections as well as to plan the imminent surgery. All other peripheral areas can be studied routinely for grading and classification of suspected vascular lesions using contrast as needed.

Ultrasound

Stroke due to cerebrovascular disease is a common cause of both disability and death. Ischemic events may be secondary to non-stenotic plaque or to significant stenosis. Plaque may be a source of microemboli, thus, it is important to have diagnostic techniques to detect these changes in the carotid vessels.

Non-invasive testing has been developed to better evaluate changes of the carotid bifurcation. The current state of the art is Duplex scanners—real time B scan imaging with pulsed Doppler. However, until their development, a battery of tests was often used—ocular plethysmography, carotid phono-angiography, bidirectional, peri-orbital, and direct carotid Doppler. The earlier techniques are sensitive to lesions of greater than 60% stenosis, but not to smaller degrees of stenosis.

The development of high resolution transducers in the 7.5-10 mHz range vastly improved image quality. As opposed to earlier scanners with 5 mHz transducers, information about plaque as well as Doppler placement could be obtained. The 7.5 and 10 mHz transducers are designed for optimal visualization of the carotid bifurcation (Figure 1).

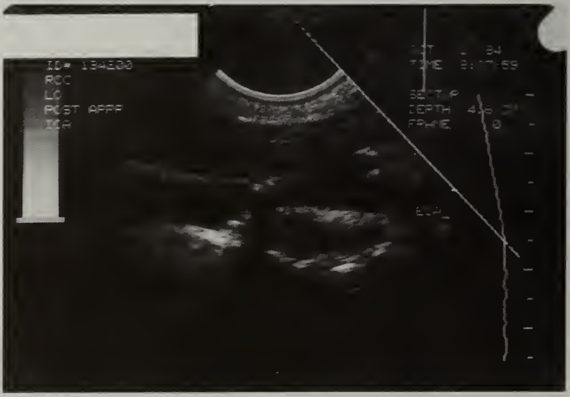


Figure 1
Scan demonstrating plaque and stenosis at bulb involving origin of internal carotid artery.

Non-invasive carotid evaluation begins with real time imaging of the carotid and its branches. The patient lies supine and scanning is performed in sagittal and transverse planes. The image is recorded and thus serves as a guide for placement of the Doppler sample volume. The Doppler signal is processed by a spectral analyzer, and the examination produces anatomic and physiologic information. The Doppler examination includes the common carotid, bifurcation, and the external carotid artery and internal carotid artery.

The results are evaluated as normal, minimal stenosis (1-15% stenosis), mild stenosis (16-49%) which is not hemodynamically significant, moderate to severe stenosis (50-99%) which is hemodynamically significant, and total occlusion (Figures 2 and 3).

The results have been compared to angiography as the standard. Zierler, et. al., reported that the sensitivity (the ability to detect any degree of carotid disease) was 97%. The specificity (the ability to recognize the absence of disease) was 84%. They have also recorded a sensitivity in recognizing significant disease (greater than 50%) of 95%.

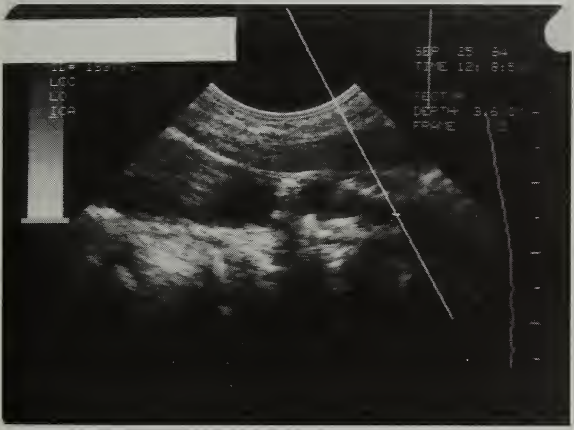


Figure 2
Scan showing plaque and stenosis of internal carotid artery.

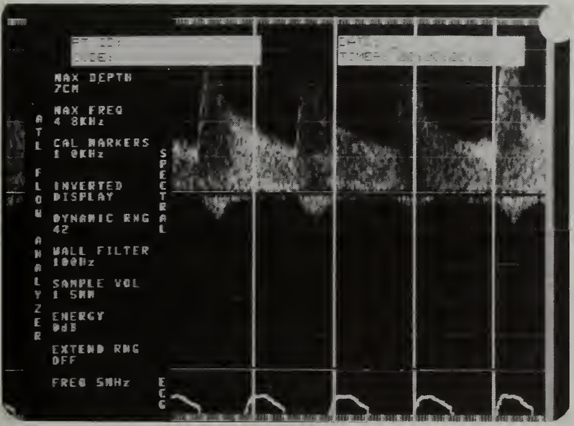


Figure 3
Doppler scan demonstrating plaque and stenosis of internal carotid (same case).

Duplex scanning of the carotids is of most value in patients with an asymptomatic bruit or with non-focal neurologic symptoms. In these patients, carotid evaluation should begin with a duplex examination. A negative examination will eliminate the need for angiography in many patients. Those who have significant stenosis on the duplex examination can be referred for angiography. Non-significant lesions can be followed with ultrasound. The diagnosis of carotid occlusion eliminates the need for angiography.

Our experience at St. Vincent's Medical Center is in keeping with the experience of the literature. Duplex scanning is used for asymptomatic bruits, in patients with TIA's who refuse invasive studies, and in some patients scheduled for non-cerebral vascular surgery (for example, coronary bypass surgery). Patients with focal defects or positive ultrasound scans may then have angiography.

Nuclear Medicine

Nuclear medicine procedures are of particular benefit in the geriatric age group since they require no patient preparation or premedication, carry no risk and are well-tolerated without discomfort. Often the study supplies an answer to a clinical problem without needing to resort to a more invasive or potentially hazardous alternative procedure.

Radionuclide angiocardiography is ideally suited to patients in the older age group because it is a simple, non-catheter procedure requiring a small volume injection of about 1 ml. of tagged Technetium red blood cells into a peripheral vein. It takes only a few minutes for the complete procedure. Moreover, it avoids the risk of using contrast material, and can be performed at the bedside using a mobile scintillation camera, without moving the patient into the Radiology Department. Intravenously administered radiopharmaceuticals can demonstrate venous obstruction such as thrombosis and early superior vena cava syndrome. In the arterial phase, aneurysms and stenotic or occluded major vessels can be discerned.

Myocardial contractility can be evaluated by labeling the patient's red blood cells with Technetium-99m Pertechnetate and imaging the cardiac blood pool. By using a computer gated to the R wave of an electrocardiogram, a series of twenty-five images is recorded during each heart beat for about 600 beats, each starting at the R wave or approximately end-diastole. The first frames of the 600 beats are added together to produce a high resolution image. Likewise, all of the second frames are added together and so on through twenty-five frames. The result is a series of twenty-five high resolution images representing the contracting heart which can be displayed in motion much the same as a continuous loop movie. A volume curve is also generated, from which the ventricular ejection fraction is calculated. The images and curves allow for various other analyses also. The main value of this study is that it provides for an assessment of cardiac chamber size, shape and regional wall motion, with the ejection fraction being an index of myocardial contractility. Thereby, the impact of coronary artery disease and its complications on myocardial performance can be assessed, as well as the effects of valvular disease, pulmonary, metabolic and other disorders which may modify cardiac function. Serial studies are useful for prognosis and to monitor the response to therapy. Multigated cardiac blood pool imaging is especially valuable in elderly patients with complex cardiovascular and pulmonary disease. If a mobile camera with an onboard, dedicated computer is available for bedside use, patients can be studied without danger of disrupting intravenous lines, indwelling catheters, monitoring and life-support systems which preclude moving the patient to another department.

Other Nuclear Medicine procedures for the diagnosis of cardiovascular diseases that are commonly seen in the elderly include lung imaging for evidence of pulmonary embolism and imaging of the heart with Thallium 201 or Technetium 99m Pyrophosphate for detection of the presence and extent of myocardial infarction.

Digital Subtraction Angiography

Digital subtraction angiography (DSA) is a computerized mode of vascular imaging which creates the computerized visualization of blood vessels by a system of digital computerization subtraction of bones and soft tissues from the images, leaving and enhancing the vascular structures. This process allows for the visualization of the major vascular systems from a simple intravenous injection. This procedure can be done on an out-patient basis. The DSA unit can also be used in conjunction with the conventional angiographic equipment. The advantage of DSA is the use of lesser contrast volume with a more limited invasive procedure and a lesser degree of discomfort and morbidity for the patient.

The intravenous angiography of the aortic arch and the extracranial cerebral circulation offers an accurate screening test for elderly patients with symptoms of cerebral ischemia. In most cases, the atherosclerotic changes and narrowing at the carotid bifurcation is adequately demonstrated so that there is no further need for additional selective arteriography studies. This is a cost-effective feature in the diagnostic work-up of the patient.

Intravenous carotid DSA has been coordinated with ultrasonic carotid imaging and Doppler spectral analysis, which has established an excellent screening tool for confident identification of the carotid bifurcation and demonstrates minimal plaque formation in carotid arteries. This eliminates the need for selective arteriography. If duplex Doppler scanning shows a significant carotid stenosis and an endarterectomy is contemplated, an intra-arterial DSA or selective arteriogram may be a more definitive pre-operative imaging procedure.

Digital subtraction is also used at this time in cardiac studies such as wall motion and ejection fraction determinations (Figures 4 and 5). The coronary arteries can be visualized with this technique and post-operative coronary bypass evaluation can be obtained by DSA. Techniques now being developed to evaluate coronary vessel disease may someday replace coronary artery catheterization.

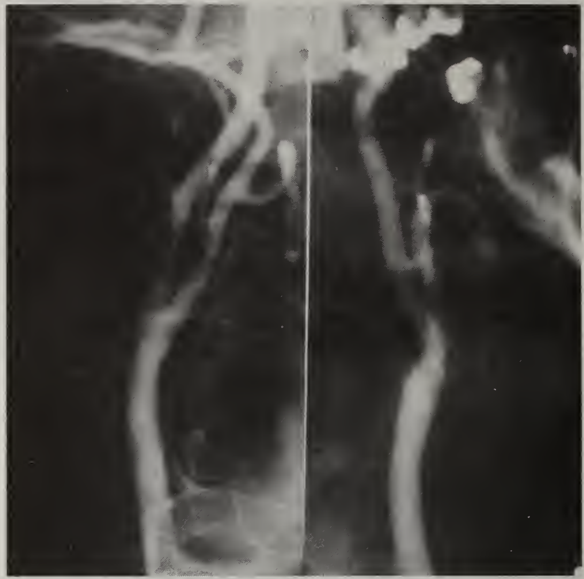


Figure 4
Digital Substraction Angiography

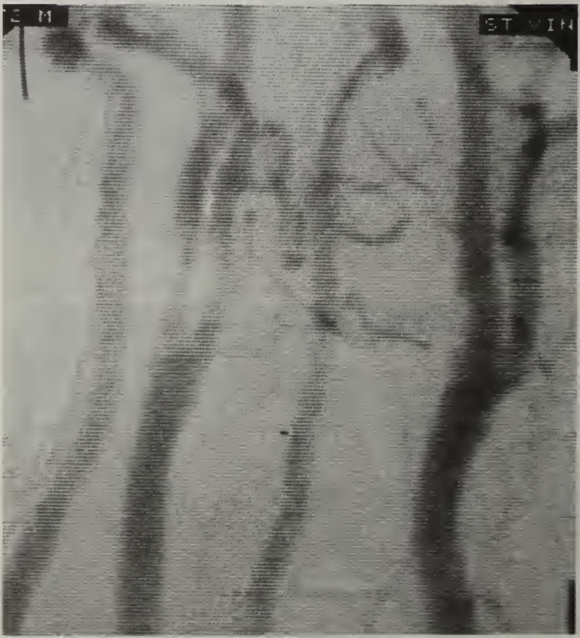


Figure 5
Digital Subtraction Angiography

Digital subtraction arteriography has also been established as a method of visualization of pulmonary arterial occlusion in pulmonary embolization and infarction.

The number of our patients having an intravenous carotid DSA has recently declined. In 1983, during the months of July, August, and September, we examined 85 patients, but in the same period of 1984 only 46 patients, representing a decrease of 46%. The answer, we believe, is given by another figure of statistics: in the same three months, the number of carotid ultrasound and Doppler examinations has increased by 45%, from 58 to 85 patients. The perfection of this non-invasive carotid imaging and Doppler blood flow evaluation by spectral analysis created a new screening test which can identify normal carotid bifurcations or minimal plaque formation in patients who, then, no longer need angiography. If, on the other hand, duplex scanning shows a significant stenosis and endarterectomy is indicated, selective arteriography is often preferred as more definitive pre-operative vascular imaging. Never-the-less, intravenous carotid DSA remains a safer, less expensive, and in most cases, perfectly adequate alternative to conventional carotid arteriography.

Cerebral Vascular Disease

The physician and the radiologist must decide which procedure to perform to outline the extent of the cerebral vascular disease, if surgery is anticipated. Intravenous DSA requires breath holding, cessation of swallowing, and good cardiac output. A patient who has had a recent stroke may not be able to cooperate for performing intravenous DSA, requiring conventional intra-arterial angiography, either using DSA or films, for good visualization of both extra- and intra-cranial cerebral vessels. Of course, there are increased risks with intra-arterial angiography with advancing age of the patient. Since intravenous DSA uses large amounts of contrast, conventional angiography may also be considered in patients with renal compromise and CHF.

Intra-arterial DSA requires a small volume of contrast medium because of its improved contrast resolution and also requires less selective catheter placement, providing images of comparable quality. Other advantages of intra-arterial DSA are rapid positioning of the patient and immediate viewing of the images, as well as reduced film cost. In addition, multiple views can be performed at one sitting, since the contrast material volume is reduced by 50 to 60%. Conventional film arteriography with selective catheterization of the vessels may have to be considered, especially in patients suspected of having carotid bifurcation disease even though the ultrasound is negative, and also for visualization of intra-cranial circulation or small vessel disease. Conventional film arteriography is still very much required for pre-surgical evaluation of cerebral aneurysms, AVM's, intra-cranial tumors, and a few other intra-cranial conditions, since intravenous DSA and non-selected intra-arterial DSA have limitation factors such as superimposition of vessels.

In patients with cerebrovascular disease, the CT scan is often the first study performed. The CT scan provides the location and extent of cerebral infarction and indicates the presence or absence of surrounding edema and mass effect (Figures 6 and 7). It is also able to differentiate between pale and hemorrhagic infarcts. In the first 48 hours, the CT scan is unable to detect cerebral infarction in most cases, an area where MRI will be useful. CT scanning is also less reliable in detecting brain stem infarction because of small size and bone artifact. CT scanning will also detect other intra-cranial lesions such as subdural hematomas and tumors.

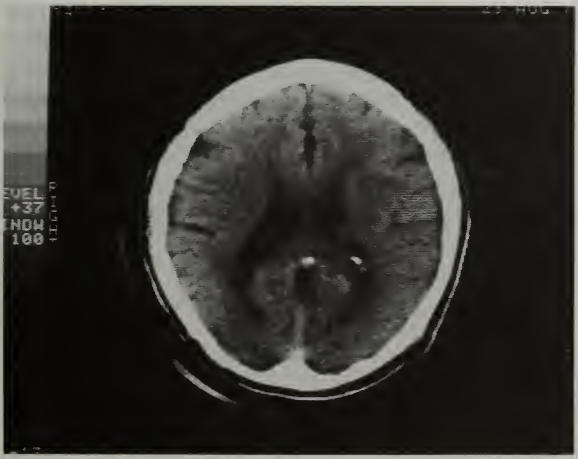


Figure 6
NON-CONTRAST CT: An ill-defined low density area in the left occipital lobe along its medial aspect with anterior displacement of glomus of the choroid plexus.

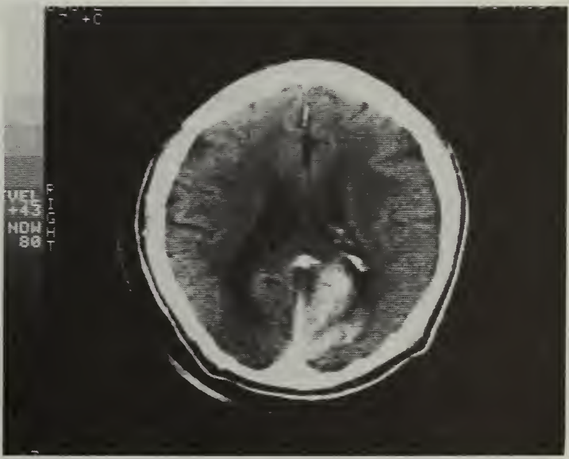


Figure 7
CT SCAN FOLLOWING CONTRAST INFUSION: Showing contrast enhancement, findings consistent with acute cerebral infarction in the distribution of left posterior cerebral artery.

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Cardiac Surgery in the Elderly

VANN W. BRUNSON, M.D., MANUEL C. PUN, M.D., EVERETT C. COOPER, M.D., STEVEN D. HERMAN, M.D. AND ROBERT W. BERRY, M.D.

ABSTRACT—Our approach to open-heart surgery in the elderly has consistently been aggressive. We therefore analyzed results in 100 consecutive patients aged 70 and over, comparing them to 738 younger patients, over a 5 year period. The 838 patients were divided into a "high-risk group" and a "non-risk group." Complications were also reviewed.

Mortality in the non-high risk coronary bypass patients was 1.3% under age 70, and 0% in those age 70 or over; while in the high risk coronary bypass group, it was 6.8% under 70 and 12.1% in those 70 or over. Mortality for valve surgery was 8.3% under 70, and 12.1% in patients 70 or over.

From our data, we conclude that age should not be considered a contraindication to cardiac surgery, especially in males. Incidence of postoperative complications is higher over age 70. Our results lead us to recommend consideration of surgical intervention earlier in the natural history of patients with heart disease.

Introduction

In the United States, current life expectancy at age 70 is over 15 years for females and 11.5 for males.[1] This expanding segment of our population, many of whom are enjoying productive lives, has demanded a more aggressive approach to their medical and surgical care. Therefore, if appropriate indications exist, and risks are reasonable, cardiac surgery should be considered an option to improve longevity and quality of life for them.

In this report we analyze our experience in a group of 100 consecutive cardiac surgery patients age 70 and over, comparing them to a larger group of younger patients undergoing the same type of cardiac surgical treatment in the same time period, to see if our aggressive approach was justified.

Methods

It has been standard practice at St. Vincent's Medical Center to enter all data in cardiac surgery patients in a computer system customized for our institution. From November 1979 to October 1984, 100 consecutive patients age 70 or over at the time of surgery, were selected. This patient population was then divided into two groups. The first group consisted of those patients who underwent coronary artery bypass surgery only (CABG). The second group consisted of those who underwent single or multi-

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VANN W. BRUNSON, M.D., Assistant Resident, General Surgery, Department of Surgery; MANUEL C. PUN, M.D., Fellow in Cardiology, Department of Medicine; EVERETT C. COOPER, M.D., Chairman, Department of Medicine; Chief, Division of Cardiology; STEVEN D. HERMAN, M.D., Chief, Division of Thoracic and Cardiovascular Surgery, Department of Surgery; ROBERT W. BERRY, M.D., Attending Thoracic and Cardiovascular Surgeon, Department of Surgery; all of St. Vincent's Medical Center, Bridgeport, CT.

ple valve replacement, with or without associated coronary bypass. All patients having CABG or valve replacement surgery during the same time period, who were under age 70, were compared with respect to mortality. Complications were compared by selecting a block of 200 consecutive patients undergoing CABG or valve replacement in the past two years.

Data on all patients was further analyzed by the individual chart review, comparing morbidity and mortality in relation to age and the surgical procedure. Mortality was defined as including all patients who expired within 30 days of the surgical procedure.

A subset of our coronary artery bypass (CABG) patients was defined as "high-risk", based on the following criteria:

1. Unstable angina requiring intravenous nitroglycerine or intra-aortic balloon pump support preoperatively.
2. Left main coronary artery occlusive disease (>70% narrowing).
3. Reoperation (history of previous cardiac surgery).
4. Recent or ongoing myocardial infarction.
5. Diminished cardiac function (ejection fraction <30%).

Regardless of age or other medical conditions, patients who did not fit in the above categories were considered as "non-high risk."

Results

Age 70 and Over

In this group of 100 patients, 67 had coronary bypass surgery only, and 33 had valve replacement surgery, with or without concomitant bypass. The overall mortality was 8/100, or 8% in the entire group. There were 4 deaths in the 67 coronary bypass (CABG) patients (5.9%)-(Figure 1). There were 4 deaths in the 33 valve patients (12.1%)-(Figure 2).

39 out of 67, or 58.2%, of the CABG patients were in the high-risk group. All 4 deaths were in this group, for a mortality of 10.2%. The 43 males accounted for one death (2.3% mortality), and the 24 females had 3 deaths (12.5% mortality). Of the 4 patients who died, one had unstable angina and three had left main coronary occlusive disease. There were no deaths in the non-high risk group (Figure 3).

Of the 33 patients having valve surgery, 14 were male and 19 were female. There were 4 deaths (12.1% mortality), all female (Figure 4). Of the four who died, two had previous open-heart surgery (one infected prosthetic valve), and one was 82 years old requiring double valve replacement.

In the 92 survivors from the original 100 patients age 70 and over, there were 20 significant complications in 15 of them (16.3%), prolonging hospital stay in 9 (Table 1).

Under Age 70

During the same time period between November 1979 and October 1984, there were 738 patients under the age of 70 undergoing open-heart surgery. 642 had coronary bypass only, and 96 had single or multiple valve replacement surgery, with or without concomitant coronary bypass. Overall mortality was 30/738 (4.0%). 22 deaths were in the CABG group of 642 patients (3.4%)-Figure 1), and 8 were in the 96 valve surgery patients (8.3%)-(Figure 2).

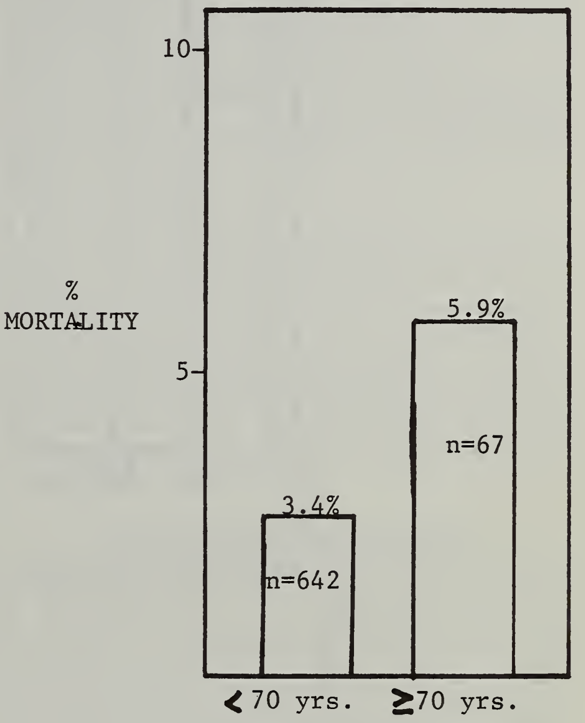

Figure 1
%Mortality in 709 Coronary Bypass Patients.

In the CABG patients, 251/642, or 39.1%, were in the high-risk group. Their mortality was 6.8% (Figure 4). In non-high risk patients, there was a 1.3% mortality rate (Figure 3). In the 503 males, there were 15 deaths (3%), with 12 of them in the high risk group. In the 139 females, there were 7 deaths (5%), with 5 in the high risk group.

The 96 valve surgery patients consisted of 45 males and 51 females. The 8 deaths in this group gave an 8.3% mortality (Figure 2), with 5 males (11% mortality) and 3 females (5.9% mortality).

In the sample of 200 consecutive patients under age 70 analyzed for complications, there were 192 survivors. In them, there were 20 significant complications in 15 different patients (7.8%). Hospital stay was prolonged in 10 because of these complications (Table 1).

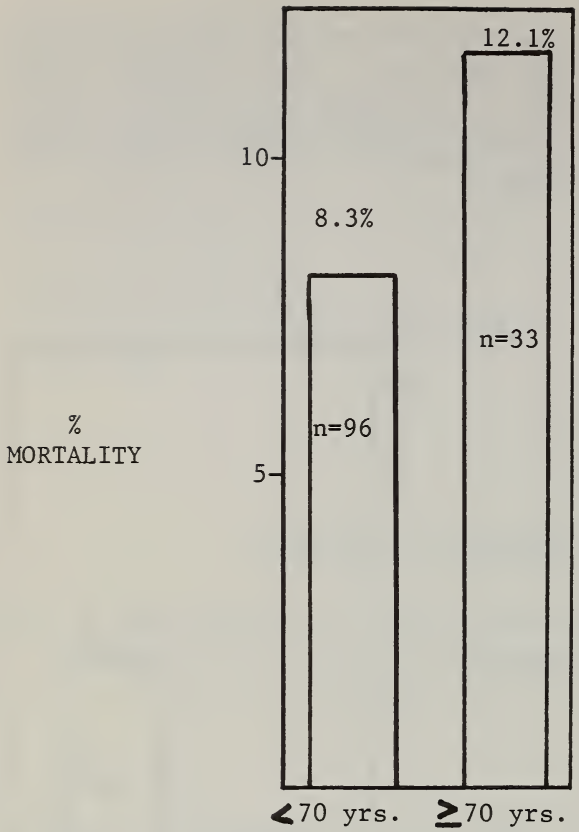

Figure 2
%Mortality in 129 Valve-Surgery Patients.

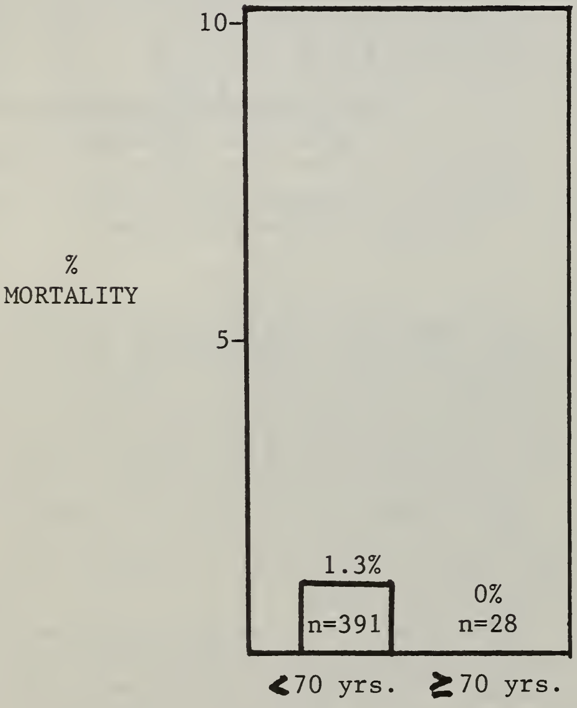

Figure 3
%Mortality in 419 Non-High Risk Coronary Bypass Patients.

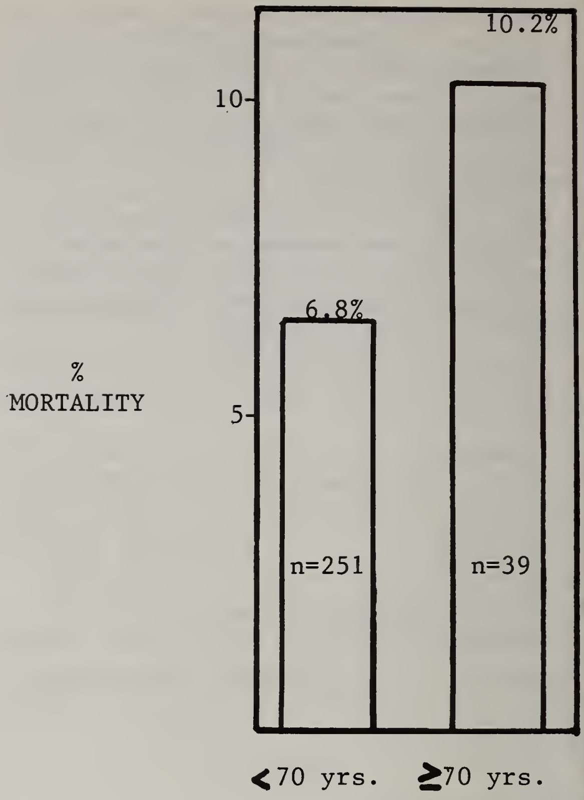

Figure 4
%Mortality in 290 High Risk Coronary Bypass Patients.

Table 1
COMPLICATIONS

	Age 70+	*Under 70 yrs.*
1.) Pulmonary emboli	2	1
2.) Re-operation for bleeding	3	5
3.) Thrombophlebitis	2	0
4.) Stroke		
—major deficit	1	0
—minor deficit	1	2
5.) Gastrointestinal bleeding	2	1
6.) Acute pancreatitis	1	0
7.) Leg wound hematoma	2	1
8.) Mediastinitis	1	0
9.) Superficial wound infection, leg	1	2
10.) Respiratory insufficiency (on respirator > 5 days)	2	2
11.) Renal failure	2	2
12.) Pneumonia	0	1
13.) Sternal dehiscence	0	1
14.) Acute psychosis	0	1
15.) Anaphylaxis to antibiotics	0	1
TOTAL	20/92 pts.	20/192 pts.

Discussion

Surgical intervention of any sort in elderly patients has traditionally been approached with caution. This view has evolved because of the inescapable facts that elderly patients have a higher incidence of debilitating concomitant illness, and have less functional reserve (commonly called "aging"). However, recent reports have shown low mortality and an acceptable incidence of complications after cardiac surgery in the elderly.[7-10, 15-17] Reported early mortality in elderly patients undergoing aortocoronary bypass has varied from 0 to 18%,[2-12] with most reports between 3 and 10%. At our institution, early mortality in the elderly coronary bypass patients was 5.9%. We were struck by the fact that 58.2% of our elderly patients were in the high risk group, compared to an incidence of 39% high risk in the large concurrent group under age 70. This significant percentage increase of high risk in the elderly presumably occurs because these patients are often considered as candidates for surgery later in the natural course of their disease than their younger counterparts.

Surgery has often been considered a last resort in this age group, as noted by Hochberg et al.[9] They reported a higher incidence of unstable angina in their elderly population, with a 12% surgical mortality. Interestingly, their matched set of patients under 70 with a similar percentage of high risk, yielded a mortality of 4%. This led to the conclusion that elderly patients may not tolerate cardiac surgery as well as younger patients in the same situation.

In our series reported here, all of the elderly CABG deaths occurred in the high risk group, with a 0% mortality in the non-high risk category. It appears that mortality in the elderly diverges from the younger age group only when they present as high risk (10.2% vs. 6.8%)-(Figure 4). Indeed, the cadre of patients randomized to surgery in the CASS report [18] are reasonably comparable to our group of non-high risk. Their reported mortality of 1.4% in patients under 65 years of age compares with our mortality of 1.3% in the under 70 age group. Our lack of any mortality in the elderly non-high risk group reconfirms that, in this classification, age itself does not seem to have any significant effect on mortality rate.

It should be noted that in our elderly CABG group, only one death occurred in a male, with three in females (2.3% vs. 12.5%). This disparity between coronary bypass surgical mortality in elderly males versus elderly females has been noted by Faro et al,[11] who reported a 28.6% mortality in females versus 6% in males, Hall et al[12] similarly demonstrated gender differences in patients over 70, with 5.3% mortality in males and 7% in females. In our series, there were no female deaths in the non-high risk group. It therefore appears that the high-risk females requiring coronary bypass surgery compose an especially vulnerable subset. Also, our data suggests that there is minimal difference in mortality in elderly males, whether they are high risk or low risk.

It is striking that 33% of the elderly patients requiring cardiac surgery in our institution needed valve replacement, as opposed to only 13% (96/738) in the under 70 age group. This suggests not only that valvular heart disease worsens with age, but also that physicians more readily consider cardiac surgery for elderly patients with valve disease and decompensation, rather than those with coronary artery disease.

Reports of valvular heart surgery have commonly defined "elderly" as 60 or 65 years of age, and quoted mortality rates from 2.7% to 18%.[13-17] Our data, from patients age 70 or older, although not directly comparable, suggests that valve surgery in the elderly (over 70) is somewhat riskier than in the younger age group (12.1% vs. 8.3%). Since three-fourths of our elderly deaths occurred in especially high risk settings, the risk in the usual patient does not seem to be greater in the elderly than their younger counterparts.

Where differences also become apparent between the elderly and the younger is in incidence of complications. There is a two to four-fold increased incidence of gastrointestinal hemmorhage, stroke, wound hematoma, respiratory failure, and renal failure. 9 of the 92 elderly survivors had their hospitalization prolonged by such complications (10%). Incidence in the 200 patients under age 70 was 10/192 (5.2%). This points out that in the elderly, hospitalization may be prolonged and postoperative management complex.

Conclusions

1. Age should not be considered a contraindication to cardiac surgery. The risks of coronary bypass surgery, at whatever age, are most dependent on the "high-risk" factors, i.e., unstable angina, >70% left main coronary occlusive disease, history of previous cardiac surgery, recent or ongoing myocardial infarction, or diminished cardiac function (ejection fraction <30%).
2. Coronary bypass surgery can be performed at the same low risk, regardless of age, in patients that do not fall into the above sub-groups.
3. In males over age 70, coronary bypass surgery can be carried out with a similar low mortality rate, even if they fall into the high risk group.
4. Cardiac surgery patients age 70 and over have more postoperative complications, and therefore longer periods of hospital stay, probably because of less functional reserve and coexisting illness.
5. As noted above, most problems appear to be in the high-risk coronary disease group. This also seems to apply to those patients with valvular heart disease. Therefore, those patients, whose cardiac disease is best treated surgically, should be selected, regardless of age, as early in the course of their disease as possible. In this way, urgent surgical intervention in an unstable patient can be avoided, leading to better survival.

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Anesthetic Considerations for Geriatric Patients

JONATHAN D. KATZ, M.D.

> . . . "when the body is weak, the lightest blow gives pain."
> *Marcus Tullius Cicero*
> *from De senectute, 45 B.C.*

An inevitable concomitant of the aging process is an increasing incidence of medical and surgical disease. In fact, of the some 26 million residents of the U.S.A. over the age of 65, fully 50% will require surgery during their remaining lifetime. It does not come as a surprise that an increasing percentage of our general surgery patients are elderly (Figure 1).

When members of the geriatric population do appear for surgery, they present special challenges for their anesthesiologist. Anesthetic complications are more frequent and more severe among patients in this age group. Age greater than 65 was one of the nine major factors with a positive correlation for cardiac risk during surgery, according to the Massachusetts General Hospital Risk Index.[1] Peri-operative mortality is considerably higher in the aged. Various studies have demonstrated a 6.2% mortality among those older than 80 years of age,[2] and 29% mortality among those older than 90 years.[3] This is

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JONATHAN D. KATZ, M.D., Clinical Associate Professor of Anesthesiology, Yale University School of Medicine; Attending Anesthesiologist, St. Vincent's Medical Center, Bridgeport, CT.

contrast to a mortality rate less than 0.75% in patients younger than 65 years.

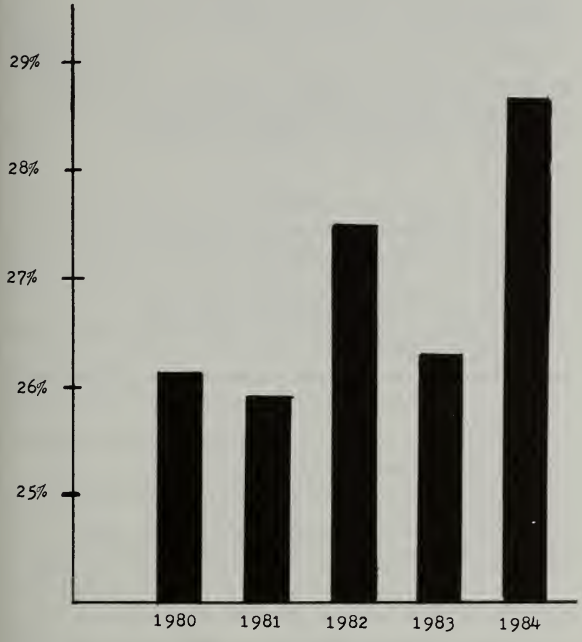

Figure 1
Percentage of surgical patients at St. Vincent's Medical Center who are older than 65 years.

Several factors contribute to this increased vulnerability to anesthetic mishap among the elderly. Most prominent are the major physiologic changes which accompany the aging process (Figure 2). These affect all organ systems and result in diminished reserve and ultimately in functional compromise. The system is incapable of recruiting compensatory mechanisms which are needed to respond to the stresses of anesthesia and surgery.

Physiology

I will briefly discuss some of the physiologic changes which are most pertinent when considering anesthetic management.

CARDIOVASCULAR SYSTEM: Probably the most frequently observed disease associated with aging, and the easiest to adequately manage is hypertension. The anesthetic literature is replete with references to support an aggressive approach toward blood pressure control in the pre-operative period in order to minimize post-operative morbidity.[5] We set as an arbitrary goal a resting blood pressure no greater than 140/90.

The other significant disability is a "cardiomyopathy" of aging. This is the result of a complex of factors, including coronary atherosclerosis and left ventricular hypertrophy. These changes result in such commonly observed dysfunctions as decreased cardiac output, congestive heart failure, and conduction disturbances.

The cardiovascular changes described, and a host of others, result in a geriatric patient who has marginal reserves and is able to recruit little, if any, sympathetic-induced response to stress. This patient can be expected to emerge slowly from anesthesia, tolerate poorly major fluid shifts, and be at increased risk for major cardiovascular failure.

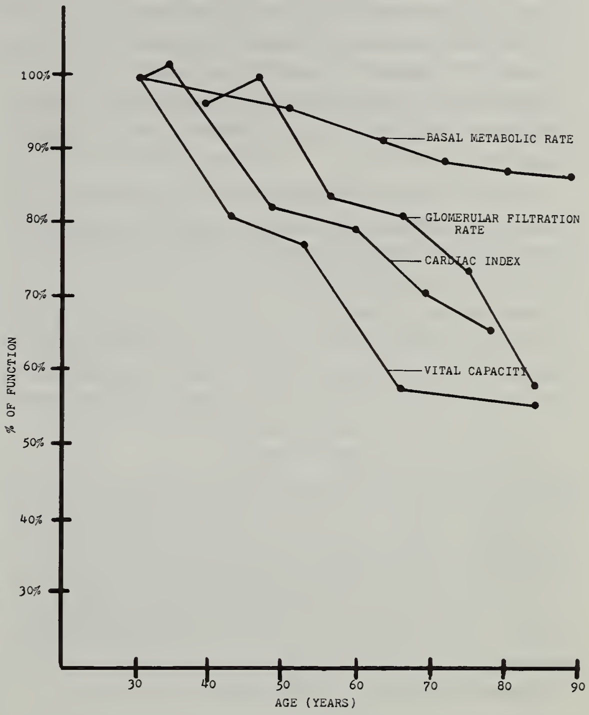

Figure 2
Physiologic function declines with advancing age. (Modified from Evans.[15])

PULMONARY FUNCTION: Functional changes in the respiratory system include deterioration in mechanical ventilation and gas exchange. The most obvious manifestation of this is an arterial blood oxygen tension diminished from normal values for younger patients.[6]

Of greater concern clinically, the aging process is associated with a markedly decreased ability to respond appropriately to hypoxia and hypercarbia. The elderly have also been observed to have decreased pharyngeal and laryngeal reflexes. These impairments put the geriatric patient at greater risk to suffer peri-operative aspiration pneumonitis and make him more likely to suffer respiratory failure and to require post-operative mechanical ventilation.[7]

RENAL SYSTEM: Degenerative changes associated with aging produce a decrease in renal plasma flow. There is a progressive decrease in renal cortical mass and impairment in glomerular filtration and tubular function. Clinically what is observed is a decreased ability to concentrate urine, to excrete hydrogen ion, and to clear creatinine.

The clinical consequence of these perturbations is that the elderly patient is less able to adjust to either fluid deprivation or overload.[8] Similarly, electrolyte (especially sodium) imbalance is poorly compensated and tolerated. There is a diminished capacity to excrete those drugs which normally rely on renal clearance. And, above all, there is a greater propensity toward renal failure.

NERVOUS SYSTEM: Every component of the central, peripheral and autonomic nervous system exhibits deterioration with age.

Atrophic changes produce decreases in functional brain mass. The elderly patient is more sensitive to anesthetic medications and more susceptible to central nervous system side effects of other drugs.[9]

Deterioration of the autonomic nervous system results in a blunting of the neural compensatory mechanisms which normally respond to stress. This serves to exacerbate the previously described failure of the individual organ systems to respond to stress during anesthesia and surgery.

PHARMACOLOGY: There are important pharmacokinetic and pharmacodynamic changes associated with aging. There is decreased plasma binding, decreased metabolism, and decreased renal clearance of most drugs. Therefore, a given dose of medication will be associated with a higher and more protracted blood level in the elderly patient. And, probably as a result of decreased receptor density, the blood level necessary to produce a given response is diminished in the aged.

Clinically, the geriatric patient is more sensitive to medication, has a more prolonged response, and is more easily overdosed. There is a marked decrease in requirement for anesthetics and recovery time from anesthesia is prolonged. For example, the dose of diazepam necessary to achieve drowziness in patients 80 years of age is 25% of that necessary in patients younger than 40 years.[10] The half life of diazepam in patients 80 years of age is 450% greater than that of patients who are 20 years old.[11]

Preoperative Evaluation

As outlined in the previous sections, the geriatric patient is more likely to suffer from hypertension, congestive heart failure, cardiac arrhythmias, chronic pulmonary disease, and metabolic and electrolyte disorders. In treatment of these commonly observed diseases, and others, the elderly patient usually takes a number of medications. In fact, the average geriatric patient receives some 13 prescription medications per year.[12] Additionally, these patients often also utilize any of a myriad of over-the counter drugs. Unfortunately, it is not unusual for them to be unaware of what medications and what dosage they are using. The potential for drug-related morbidity is enormous, in the form of omitted medications, inappropriate dosage, or complex drug interactions. An accurate and complete drug history is essential.

Table 1 lists some of the medications commonly employed in the geriatric population. The question arises whether medications should be discontinued in the pre-operative period. In the past, opinions on this issue have differed considerably. The current feeling of most authorities is that the majority of medications, especially those for blood pressure control, should be continued up to, and including, the morning of surgery.[13] The major exceptions to this generalization are the monoamine oxidase (MAO) inhibitor class of antidepressants which should be discontinued two weeks prior to planned surgery.

Table 1

MEDICATION COMMONLY EMPLOYED IN THE GERIATRIC POPULATION AND THEIR ANESTHETIC IMPLICATIONS

1. Diuretics—hypokalemia, hypovolemia.
2. Tranquilizers, alcohol—dependence, withdrawal.
3. Antidepressants—interaction with anesthetic drugs, disturbance of myocardial conduction.
4. "Mycin" antibiotics—potentiation of neuromuscular blocking drugs.
5. Echothiophate eye drops—interference with succinylcholine metabolism.
6. Calcium channel blockers—disturbance of myocardial conduction.
7. Beta blockers—predisposition to heart failure.
8. Aspirin (frequently overlooked as a medication)—bleeding disturbance.
9. Lithium—potentiation of neuromuscular blocking drugs.
10. Cimetidine—interference with metabolism of diazepam, inderal.

The pre-operative laboratory evaluation must be thorough. The current trend, encouraged by medicoeconomic pressures, is towards limiting the scope of "routine" pre-operative screening studies. Nevertheless, elderly patients, even those, "healthy" and asymptomatic, should have: hemoglobin or hematocrit, electrocardiogram, chest X-ray, and BUN/glucose. In some centers, arterial blood gases are also part of a "routine" screen in this age group. Additional laboratory tests must be ordered when the history or physical examination indicates the slightest deviation from "healthy." For example, serum electrolytes must be available when the patient is taking diuretics. Events in the operating room, such as the use of muscle relaxants, mechanical ventilation, and intravenous fluid administration, will exacerbate any electrolyte disturbance resulting from chronic diuretic use.

A pre-operative physiologic assessment probably provides the most pertinent information toward predicting intra-operative behavior and post-operative morbidity and mortality. Del Guercio and Cohn did hemodynamic profiles on 148 elderly patients who had been previously "cleared" for surgery.[14] They found 34 patients (23%) who had significant functional defects which, by their criteria, made them unacceptable candidates for the proposed surgery. Nineteen of the patients had the surgery cancelled for non-surgical interventions. There was 100% survival among the seven patients who underwent lesser operations. And there was 100% mortality among the remaining eight patients who had the major surgery as originally proposed.

Operative Management

Because of the pharmacologic factors considered above, premedication must be administered judiciously. In many cases no preoperative sedative medication is necessary. Where indicated, diazepam (5 mg.) orally with a sip of water, or the intramuscular injection of diphenhydramine (Benadryl) (25- 50 mg.) provides excellent and safe tranquilization.

Wherever the proposed surgery permits, regional anesthesia should be elected over general anesthesia. However, while administering the local anesthetic, the physician must be constantly reminded of the lower therapeutic ratio of local anesthetics in the elderly. A careful tally must be kept of the total milligram dosage administered to avoid approaching toxic levels. Frequently, additional intravenous sedation is called for, but this supplement can not substitute for an inadequate regional anesthetic. The elderly patient may respond paradoxically to attempts at intravenous sedation and instead manifest excitation. Intravenous diazepam in 2 mg. aliquots generally provides safe sedation.

When considering general anesthesia, one must be reminded of the old adage, "There is no minor anesthesia, only 'minor' surgery." There is no good literature that indicates that one general anesthetic technique or agent provides a margin of safety over any other. Rather, a series of contra-indications may dictate that a certain anesthetic approach be selected.

A review of specific anesthetic protocols is beyond the scope of this discussion. However, we can make certain generalizations. Anesthetic induction and emergence will be prolonged and more likely associated with hemodynamic instability. Wide swings in blood pressure are not at all uncommon. The requirements for fluids and electrolytes must be accurately calculated and administered. Extensive monitoring, including arterial and pulmonary artery lines may be required even in 'minor' surgery. Special attention must be paid to positioning of the patient during the surgery.

Post-Operative Care

The transition to the recovery room may be the most challenging to the patient during the entire peri-operative period. Upon emergence from anesthesia, it is not at all unusual for the patient to manifest extreme hypertension. If left untreated, heart failure, myocardial infarction, or cerebrovascular accident may result. Sublingual nitroglycerine often provides rapid and gentle moderation of the hypertensive crisis. If unsuccessful, and the hypertension is extreme (systolic B.P. greater than 220 mm. Hg.) we resort to sodium nitroprusside for immediate control. Within minutes this medical emergency should be resolved, and we will gradually substitute hydralazine or alpha-methyldopa or whatever chronic B.P. medication the patient normally receives. At the same time, other possible contributors to the hypertension, especially pain, must be considered and treated.

The other major area of concern in the immediate post-operative period is respiratory management. The risk of respiratory depression, aspiration, and respiratory failure is enhanced in this age group. All mechanical parameters must be fulfilled before we consider weaning from mechanical ventilation and endotracheal intubation. This may require as much as 24 hours of intensive respiratory therapy in the recovery period. When such a post-operative course can be anticipated, it is helpful to pre-warn the patient and family members.

Conclusion

Persons older than 65 years of age are seen in growing numbers among our surgical patients. The risks for complications and death in the peri-operative period are increased in this population. Thorough pre-operative assessment with aggressive correction of physiologic disturbances is the cornerstone of optimal surgical management of these patients.

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Abdominal Aortic Aneurysm Resection: A Ten-Year Community Hospital Experience

DENNIS D. WILCOX, M.D.

Surgical intervention in the elderly with abdominal aortic aneurysms has undergone major changes in recent years. Once a diagnosis of an aneurysm has been made the risk of rupture and death rise sharply over time. Aggressive surgical management becomes imperative, especially in the symptomatic patient who will most likely die if surgery is withheld or postponed. With improved survival, abdominal aortic aneurysm resection has become more frequently performed on older people. This is a review of the last ten years' experience at St. Vincent's Medical Center.

Materials and Methods

A retrospective review of patients undergoing surgery for abdominal aortic aneurysms at St. Vincent's Medical Center during a ten-year period between January 1974 through December 1983 was made. One hundred and thirty-three patients had abdominal aortic aneurysm resections. Of these, 109 were male and 24 were female. The ratio of male to female was 4.5:1. The mean age for the entire group was 67.7 years.

The series, when broken down into subgroups according to age, showed 26 patients 59 years of age and younger, 49 patients aged 60 to 69, 45 patients aged 70 to 79 and 13 patients 80 years of age and greater. Forty-four percent of the patients were 70 years of age and older.

Elective aneurysectomy was performed on 86 patients. Thirty-one patients were operated on as an emergency for acute symptoms, were found at operation to have nonruptured abdominal aortic aneurysms and were classified as acute-urgent. Sixteen patients were operated upon for acute-ruptured aneurysms.

Seven attending vascular surgeons, with general surgery resident staff assistance, performed all 133 cases.

The overall mortality rate for the series was 12.8%. Five patients died following elective surgery (5 of 86 = 5.8%). Three patients died following acute-urgent surgery (3 of 31 = 9.8%). Nine patients undergoing surgery for acute-ruptured abdominal aortic aneurysms died (9 of 16 = 56.3%).

Mortality of patients within each subgroup for age was analyzed. None of the 26 patients 59 years or less died, for a mortality in this subgroup of zero. Of the 49 patients aged 60 to 69, nine patients died, for a mortality of 18.4% (9/49). Of the 45 patients aged 70 to 79, seven patients died, for a mortality in this subgroup of 15.6% (7/45). The oldest, albeit the smallest subgroup of 13 patients 80 years or older, suffered only one death for a mortality rate of 7.7% (1/13). The overall mortality of patients 70 years of age or greater was 13.8% (8/58), compared to 12% (9/75) for those under age 70. See Figure 1.

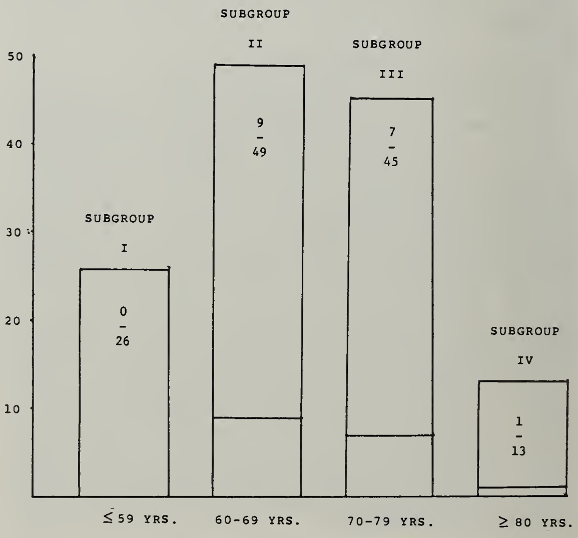

Figure 1
Mortality Within Subgroups

DENNIS D. WILCOX, M.D., Resident in Surgery, Department of Surgery, St. Vincent's Medical Center, Bridgeport, CT.

One hundred thirteen charts of 133 patients were available for review of further details.

Twenty-four patients had a known history of abdominal aortic aneurysm for six months or longer. Of these 24 patients, 12 patients had known aneurysms for longer than two years. Four of these died either intra- or post-operatively. None of the other 12 patients died following surgery, and there were no patients in this group who had ruptured.

Five patients had a positive family history of abdominal aortic aneurysm in either parents or siblings. Only nine charts documented a definite negative family history of abdominal aortic aneurysm; the remainder were ambiguous.

Associated symptoms in the charts reviewed are listed in Table 1. Fifteen patients were asymptomatic. Twelve patients were found to have abdominal aortic aneurysms during a work-up for another problem. Fourteen patients presented to the Emergency Department in a state of shock, and six of these had full cardiac arrests. Seventeen patients were found to have abdominal aortic aneurysms during vascular evaluation, six of these were for claudication. Almost all patients had a pulsatile mass in the abdomen. Seven were noted to also have a bruit.

Table 1
ASSOCIATED SYMPTOMS

SYMPTOMS ON ADMISSION	*NUMBER OF PATIENTS*
ABDOMINAL PAIN	32
BACK PAIN	11
GASTROINTESTINAL COMPLAINTS	8
CALF PAIN	5
DYSPNEA	3
CHEST PAIN	2

Past medical history: the number of deaths associated with each disease and the relative mortality for each is shown in Table 2. Social habits were also reviewed, but not always recorded in the history and physical. Fifteen admitted to social drinking, and five to chronic alcoholism. Only 15, however, denied alcohol use. Forty-five cigarette smokers were recorded and found to have smoked on average two packs per day for more than 30 years.

The pathological severity of the aortic disease encountered at surgery can be inferred by the type of graft or procedure performed (See Table 3). Fifty-seven percent (64/113) of these patients had enough distal aorto-iliac disease to require a bifurcated graft, and another 10 patients (8.8%) required femoral grafts.

Forty patients suffered complications, and these are listed in Table 4.

Table 2
PAST MEDICAL HISTORY

HISTORY	*NUMBER OF PATIENTS*	*DEATHS*	† *MORTALITY*
HYPERTENSION	47	6	12.70%
ARTERIOSCLEROTIC HEART DISEASE	16	0	0
STATUS POST ACUTE MYOCARDIAL INFARCTION	16	1	6.25%
STATUS POST CORONARY ARTERY BYPASS	5	0	0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	16	2	12.50%
CANCER	10	2	20.00%
PERIPHERAL VASCULAR DISEASE	7	1	14.30%
STATUS POST VASCULAR SURGERY	9	2	22.20%
DIABETES MELLITUS	7	0	0
STATUS POST COLECYSTECTOMY	14	2	14.30%
STATUS POST COLON RESECTION	3	0	0
PEPTIC ULCER DISEASE	5	0	0
STATUS POST GASTRIC RESECTION	3	0	0
STATUS POST CEREBRAL VASCULAR ACCIDENT	5	2	40.00%

Table 3
PATHOLOGY

TYPE	*NUMBER OF PATIENTS*
TUBE	35
BIFURCATED	64
GOLDBLATT KIDNEY RESECTED	3
AORTO-BIFEMORAL BYPASS	7
AORTO-FEMORAL AND ILIAC BYPASS	3
AORTO CAVAL FISTULA CLOSURE	4
AORTO LEFT RENAL VEIN FISTULA CLOSURE	1
RENAL ARTERY STENOSIS REPAIR	3
AXILLARY BIFEMORAL BYPASS	3

Table 4
COMPLICATIONS

40 PATIENTS HAD COMPLICATIONS:	*NUMBER OF PATIENTS*
A-LINE SITE SKIN INFECTION	1
MULTIPLE SYSTEM FAILURE	6
CARDIAC ARRYTHMIA	5
ILEAL OR FEMORAL A. OCCLUSION	3
CEREBRAL VASCULAR ACCIDENT	2
ACUTE MYOCARDIAL INFARCTION	2
RESPIRATORY FAILURE ONLY	2
SPINAL CORD PARESIS	1
MESENTERIC ISCHEMIA	1
CARDIAC ARREST ONLY	2
CHRONIC RENAL FAILURE	3
CONGESTIVE HEART FAILURE	1
DELIRIUM	2
DECUBITUS ULCERS	4
LEG EDEMA	1
SPLENIC TRAUMA/SPLENECTOMY	1
BOWEL NECROSIS	2
PNEUMONIA	1
URINARY TRACT INFECTION	1

Table 5

AGE AND INDICATIONS FOR SURGERY

	ELECTIVE			*ACUTE-URGENT*			*ACUTE-RUPTURED*		
	# OF Patients	*# OF Deaths*	*% Mort*	*# OF Patients*	*# OF Deaths*	*% Mort*	*# OF Patients*	*# OF Deaths*	*% Mort*
SUBGROUP I ≤59 YRS	17	0	0	6	0	0	3	0	0
SUBGROUP II 60-69 YRS	32	3	9.4	12	1	8.3	5	5	100
SUBGROUP III 70-79 YRS	27	1	3.7	11	2	18.2	7	4	57.1
SUBGROUP IV ≥80 YRS	10	1	10	2	0	0	1	0	0
TOTALS	86	5	5.8	31	3	9.8	16	9	56.3

Discussion

Abdominal aortic aneurysms have been reported to be increasing in frequency as the age of the general population is increasing.[1] More aneurysms are being found, and found earlier, because of improved non-invasive diagnostic imaging techniques — often in the process of a work-up for other illness.

For the past 10 years, it has been recognized that the previously high surgical mortality (15%) of abdominal aortic aneurysm resection has been significantly reduced.[2,3,4] With these factors in mind, it would seem that community hospitals with the radiologic technology to diagnose, and the surgical capacity to perform major vascular surgery would be treating an increased number of abdominal aortic aneurysms. During the 10-year period of our study, 30 patients (22.6%) underwent surgery during the first five years, and 103 cases (77.4%) were done the last five years. Most of the patients in this series had symptomatic abdominal aortic aneurysms, with 15% being asymptomatic. Eleven percent were found on work-up of other problems. Nine patients had pulsatile abdominal masses noted on physical examination by their family doctor, and were referred for elective surgery. Many, however, delayed surgery more than six months and some as long as two years, and of these later patients, three came in with ruptured abdominal aortic aneurysms, and all three died. The mortality rate for patients in shock was 64.3%.

As the subgroups according to age indicate, no significant difference in overall survival was achieved between those older or younger than 70 years of age. When the subgroups are further broken down between the indications for surgery (See Table 4), important differences are appreciated. The seven patients in subgroup III that were operated upon for a ruptured aneurysm had 57.1% mortality. These results approach those of Vidal[5] et al (88%), and are attributed to decreased organ reserve in the face of hemorrhagic shock. Subgroup II however, although younger, did not benefit from their age group and suffered 100% mortality from ruptured aortic aneurysm. What does appear to be significant from our results is the greatly reduced mortality if the acute aneurysmal symptoms were associated with surgery before rupture and shock ensued, as indicated by the mortality rates for subgroups II and III of 8.3% and 18.2%, respectively.

Whittemore has associated reduced operative mortality with maintenance of optimal cardiac performance.[6] We believe that improved survival in acute-urgent abdominal aortic aneurysm surgery at our facility has not only been enhanced with the use of the pulmonary artery balloon catheter, but also by the rapidity of making the diagnosis and operating prior to rupture. This is well demonstrated in the four cases of aorto-caval fistulae — all of which survived compared with the previously reported mortality of 50% for this seemingly rare complication of abdominal aortic aneurysm. The five cases of aorto-venous fistulae occurred among 100 consecutive cases over five years, and are the highest incidence for this entity reported to date.

As Thompson showed ten years ago, decreased mortality is also related to earlier diagnosis, simplified operative techniques, improved fluid management, innovations in cardiopulmonary therapy and recognition and proper handling of unusual manifestations of aortic aneurysms.[4] That innovative cardiopulmonary therapy took place can be appreciated by the fact that only one of 16 patients with a prior history of acute myocardial infarction died following surgery, and none of the five patients who had undergone previous coronary artery bypass suffered a mortality. The fact that five patients had a strong family history of abdominal aortic aneurysm brings up the recently suggested genetic factors that may be important. Several of these patients were referred to Drs. Tilson and Seashore at Yale and were included in their human genetics study.[7] The fact that most patient's medical records contained an ambiguous family history for abdominal aortic aneurysm emphasizes the need for careful family history taking if we are to learn more about the pathogenesis and earlier prevention and treatment for this potentially devastating disease.

Reports of abdominal aortic aneurysm resection performed in community hospitals are few. Vidal and co-authors[5] in Youngstown, Ohio reported a mortality rate of 3.6% of 82 patients undergoing elective resection and 58% mortality in 38 patients operated on for rupture. Eighteen of these were in shock. Bottsford and co-workers[8] in Spartansburg, South Carolina reported 5.6% mortality in 53 elective cases and 69% mortality in 13 cases of rupture, seven of which were in shock.

Reports from larger university centers have similar results. Hicks, et al[2] reported 8.4% mortality for elective cases, 6% for urgent cases and 55% for ruptured aneurysms. Young and co-authors[3] reported 6.3% mortality in elective cases and 57% for ruptured aneurysms. Thompson, et al[4] reported 5.5% mortality for elective resections in 337 cases performed over a 20 year period.

A unique study by Pilcher, et al[9] reported on the experience in the entire state of Vermont over a seven and one-half year period. The overall mortality for elective surgery in 207 cases was 11.1%, with a nine percent mortality rate included from the University of Vermont Medical Center. The overall mortality of those reaching surgery for ruptured aneurysms was 55% for the entire state, and 46% for the University Medical Center.

De Weese[10] studied mortality rates for elective resections using Professional Activity Study (PAS) information. It was determined that in small hospitals (usually less than 100 beds), the mortality rate in 1976 was 11.1%. In medium sized hospitals (usually 100 to 400 beds), mortality was 9.2%. In larger hospitals (usually more than 400 beds), mortality was 8.5%.

In 1967 Edmunds showed that chronologic age is not as important as physiologic age in assessing the risk of aortic resection. He showed that in octogenarians the mortality rate of surgery would be less than that from rupture within six months regardless of cardiovascular status.[11] Crawford has shown a marked improvement in operative survival in recent years despite a ten fold increase in high risk patients undergoing elective surgery. Operative mortality in that series was two percent.[12] On the other hand, operative mortality, once rupture has occurred, is still unacceptably high. There seems to be no justification in delaying operative repair on the basis of age once the diagnosis has been made.

Summary

One hundred thirty-three patients underwent abdominal aortic aneurysm resection over a ten year period. Mortality for elective surgery was 5.8%. Thirty-one patients had acutely urgent resections of non-ruptured aneurysms and suffered 9.8% mortality. Of those who were operated on for ruptured aneurysms (16), 56.3% died. Patients were separated into groups according to age and were found to have no significant difference in overall survival if younger or older than 70 years. The timing of the operation before rupture occurred, regardless of age or prior illness, provided significantly improved survival. The reduced mortality in elective resections compared to the high mortality following rupture is demonstrated by our experience as well as others. We advocate an aggressive attitude towards elective aneurysm resection in all patients without significant medical contraindications. We strongly submit that surgery should not be delayed in symptomatic aneurysms regardless of age.

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Neuromuscular and Mental Manifestations of Hyperparathyroidism in the Elderly

MARVIN GARRELL, M.D., F.A.C.P.

The incidence and prevalence of physiological dysfunction and psychiatric illness rise progressively with increasing age. Physical abnormalities are known to disrupt psychiatric homeostasis. Dysfunction in practically every organ system can have an impact on cognitive and neuromuscular function. Unfortunately, diagnostic nihilism often pervades the treatment of the elderly and only too often mental deragement[1] with, or without, gait impairment[2] is concluded to be due to multiple cerebral infarcts or Alzheimer's-type dementia. Adversely contributing to these oversights is terminological chaos involving such terms as confusion, organic brain syndrome, senility, cerebral arteriosclerosis, and delirium, all of which have been sorted out and reclassified in the American Psychiatric Association's publication of DSM III.

The elderly person whose clinical presentation suggests neuromuscular and/or mental derangement, whether chronic[3] or acute, must be evaluated as if he or she had a diagnostic state of delirium. This delirium[4] may present with either hypoactive or hyperactive psychomotor behavior. Of great consequence is the necessity to perform an evaluation for etiologic reversibility. In hyperparathyroidism, the symptoms and signs are often assigned to another system, or are vague enough to be dismissed until hypercalcemia is discovered in a screening test. The following is an illustrative case report:

A 79-year-old woman was hospitalized at St. Vincent's Medical Center, having, been found at home on the floor, conscious but unable to arise. She denied any syncopal episodes, but had been aware of generalized muscle weakness, slowed gait, and unsteadiness for three months. For eight weeks prior to admission, she had given up driving her car. A relative attested to observing memory impairment and irritability over the past six months. The patient took no medication.

Physical examination on admission revealed a gray-haired frail, elderly woman lying comfortably in bed trying to sort out place, time, and sequence of events without success. Direct questioning by the Folstein minimental status test produced zero results. Reflexes were equal and hyperactive. Blood pressure 160/90, pulse 90. There were no murmurs; the lungs were clear; the abdomen was normal; the mouth was dry. Testing of all four extremities revealed diffuse weakness. Pertinent laboratory testing revealed hemoglobin 14.1 gm/dl, sodium 144 meq/dl, potassium 3.0 meq/dl, chloride 104 meq/dl, calcium 18 mg/dl, glucose 120 mg/dl, BUN 21 mg/dl, phosphorus 2.5 mg/dl, creatinine phosphokinase 124 U/dl, T4 11.3 mcg/dl, T3 174 ng/dl, 25-hydroxy vitamin D 11 ng/dl, PTH 5890 pg/dl, immunoelectrophoresis normal.

The patient remained delirious and weak and was treated with 0/95% saline infusions and furosemide to promote calcium diuresis. Further diagnostic imaging was performed that included a bone scan, computerized axial tomographic study of the head, neck and thorax. None of these revealed any abnormality and no evidence of distortion of anatomical structures in the neck area. On the sixth hospital day, a 2 x 1 x 0.6 cm. parathyroid adenoma was excised. The adenoma was disclosed readily at the inferior pole of the right lobe of the thyroid gland. Microscopic histology was consistent with a parathyroid adenoma. Postoperative calcium has remained at about 8.2 mg/dl. The patient has attained a normal mental status; all muscular weakness has resolved, and the patient has resumed driving her car and independent living. She now exclaims that living is a joy and wonders how she could have been so irritable.

Discussion

At St. Vincent's Medical Center, nineteen patients had parathyroid adenomas excised from 1974 to 1984. Ages ranged from 24 to 82. Presenting chief complaints included weakness, irritability, dizziness, dyspepsia, abdominal pain, kidney stones, leg cramps, and forgetfulness. All were diagnosed through screening serum calcium determination. This patient, one of the nineteen, had severe

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MARVIN GARRELL, M.D., F.A.C.P., Director of Medical Education, St. Vincent's Medical Center, Bridgeport, CT; Associate Clinical Professor of Medicine, Yale University School of Medicine, New Haven, CT; Medical Director, The Jewish Home for the Elderly, Fairfield, CT.

mental and neuromuscular symptoms and signs which also were diagnosed by screening that included the serum calcium.

Summary

A 79 year-old woman who had primary hyperparathyroidism presented with muscular weakness and delirium. After surgical removal of a parathyroid adenoma, there was a dramatic improvement in muscle function and mental status. Screening biochemical tests are a necessity in the aged ill with neuromuscular and/or mental status derangement.

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Behavioral Health Risks

Major causes of morbidity and mortality in the United States are increasingly linked with lifestyle patterns and health behaviors. The Centers for Disease Control conducted a Behavioral Risk Factor Survey in 1981-83 to estimate the prevalence of certain health behaviors associated with a risk of chronic disease. The telephone survey was carried out in 27 states and the District of Columbia, and included adults 18 years of age or over. Bradstock and associates report the following results.

1. A total of 57.6 percent of respondents of both sexes reported that they never or almost never used seat belts.

2. A total of 3.9 percent of the survey population reported that they had been told they had high blood pressure and that they were still hypertensive at the time of the interview. Blacks were somewhat more likely to be hypertensive, as were older persons and those living in the Southeast.

3. Those who were currently smokers accounted for 31.5 percent of the U.S. adult population. More men reported that they smoked than women. The prevalence rate of current smokers according to state ranged from 23.7 to 37.4 percent.

4. A total of 22.5 percent of the respondents reported that they were overweight, defined as 120 percent of ideal body weight. The prevalence differed little between the sexes. In the 45 to 54 age bracket, the prevalence was 35.8 percent, which declined thereafter. A higher prevalence was reported in the eastern states.

5. A total of 11.7 percent reported that they had a sedentary lifestyle, defined as sedentary work combined with less than one hour per month of vigorous physical exercise and less than eight hours per month of light activity. The prevalence was similar in men and women, and increased among older adults.

6. A total of 8.4 percent reported heavy alcohol use, defined as an average consumption of two or more drinks per day. Sex differences were marked, with 13 percent of men and 3.9 percent of women reporting this level of use. Consumption of alcohol was lowest in the southeastern states. Acute or binge drinking, defined as consumption of five or more drinks on a given occasion in the past month, was reported by 22.7 percent. In young men, aged 18 to 24 years, the prevalence of binge drinking was 51.9 percent. Overall, 6.3 percent reported driving after drinking within the past month. Rates for men significantly exceeded those for women (9.4 percent versus 3.4 percent).

Further in-depth analysis will probably reveal that many of these individual health behaviors are part of more complex patterns of behavior and that health behavior in one risk category is associated with a high likelihood of health behaviors in other risk categories.

—(*Centers for Disease Control Surveillance Summaries,* Fall, 1985.)

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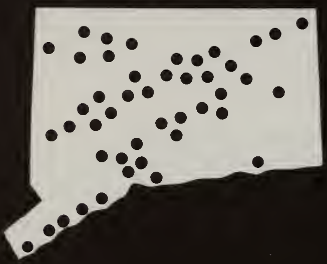

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Important Advances in Clinical Medicine
Epitomes of Progress—General Surgery

The Scientific Board of the California Medical Association presents the following inventory of items of progress in general surgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in general surgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on General Surgery of the California Medical Association and the summaries were prepared under its direction.

Arm Veins—Durable Autogenous Alternatives for Arterial Bypass

The cephalic and basilic arm veins, by virtue of their length, diameter and patency, are satisfactory substitutes for the saphenous vein in leg bypass operations. Although frequently gossamer thin, the bursting strength of arm veins exceeds 400 mm of mercury; their diameters average 5 to 7 mm and they are more uniform in caliber than their saphenous counterparts. The medially placed basilic vein spans the common femoral to the infrageniculate popliteal artery segment; the cephalic vein, when excised completely from the wrist to the deltopectoral groove, extends to the tibial vessels. Most important of all, arm veins are endothelialized, compliant and autogenous.

The test of any graft material is patency and it is here that arm veins show their desirability. The gold standard for graft patency and effectiveness is the reversed saphenous vein. Neither Dacron, polytetrafluoroethylene, human umbilical vein nor endarterectomy or balloon angioplasty has approached the long-term durability of autogenous vein. The tantalizing impulse to "go to the shelf" for a synthetic graft in the 20% to 40% of patients with an inadequate or previously excised saphenous vein should be tempered by the disappointing patency rates of nonautogenous conduits.

A recent comprehensive follow-up of arm vein grafts to the popliteal and infrapopliteal arteries has shown short- and long-term patency equivalent to that of saphenous veins. Limb salvage was the indication for 55% of the 70 operations. No in-hospital mortality was observed and fears of donor upper extremity morbidity were unfounded. Complications such as inflow and outflow occlusion and neointimal proliferation occurred infrequently and were managed as with saphenous grafts. Late aneurysmal dilatation, reported by others, occurred only once.

With so many desirable features, it is perplexing why the use of arm veins for arterial grafts has not achieved widespread popularity and application. Learning to excise and prepare these delicate vessels and to do anastomoses can be frustrating and demands patience and technique. Magnification is advisable. With a two-team approach, the operating time is about 20 minutes longer than that for a saphenous vein bypass. A successful outcome with arm vein grafts requires educating patients, surgeons, phlebotomists and vein-care teams, referring physicians and nursing personnel.

A secondary surgical procedure for graft failure does not mandate the use of a synthetic graft. In this situation, arm veins have also yielded better long-term patency than any synthetic graft. Unfortunately, some patients by this time will no longer have a satisfactory undamaged arm vein and should properly receive a synthetic conduit. Nevertheless, the advantages of autogenous grafts dictate

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that contemporary vascular surgeons be prepared to use arm veins as bypass grafts and to include them in their therapeutic armamentarium.

George Andros, M.D.
Robert W. Harris, M.D.
Burbank, California

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Needle Aspiration of the Thyroid Gland

A precise diagnosis and therapy for thyroid nodules and certain other thyroid abnormalities, such as chronic lymphocytic thyroiditis, require histologic identification. Although some physicians retain reservations, increasing evidence indicates that needle biopsy best provides this information in selecting patients for surgical and medical treatment of thyroid nodules.

Three major techniques are used for needle biopsy of the thyroid gland. Experience leads to individual preferences and the efficacy of different techniques remains somewhat controversial. Tissue that is representative of the thyroid abnormality must be obtained. *Fine-needle aspiration biopsy* can be used in nearly all situations, is best accepted by patients, has high reliability in experienced hands and is gaining in popularity. This technique requires a knowledgeable cytologist. *Large-needle aspirates* provide cellular material for *histologic* study. Experience indicates that the results of this procedure are less dependable than those from fine-needle aspiration. *Core needle biopsy* (usually with a Silverman or a TruCut needle) provides tissue for histologic study. For the latter technique, the thyroid nodule should be more than 2 cm in diameter (1.5 cm if easily accessible). This requires a small skin incision, is a slightly more complicated procedure than fine-needle aspiration and is less acceptable to patients. Core needle biopsy is highly (90%) reliable and appears to be most useful in cases that remain a diagnostic problem after fine-needle aspiration biopsy; as such, it is decisive in 15% to 20% of cases of thyroid nodules.

Fine-needle aspiration biopsy permits immediate assessment of virtually all thyroid nodules and is our preferred basic technique. Strict criteria for the adequacy of specimens are mandatory, with the presence of clumps of normal cells in at least two slides required to permit a report of a benign lesion with the fine-needle technique. Aspirates are obtained from at least six different locations of the nodule. We classify results as benign, inadequate, indeterminate and malignant, with appropriate characterizations for each category.

Cystic degenerating thyroid nodules commonly result in an inadequate specimen from needle biopsy. Biopsy by fine-needle aspiration or core needle biopsy of the solid component of such lesions following aspiration of fluid may produce an adequate specimen.

Indeterminate specimens from needle biopsy usually indicate a cellular lesion that cannot be identified as either a benign cellular adenoma or low-grade follicular carcinoma of the thyroid gland. For this and similar difficulties, including Hürthle cell lesions, core needle biopsy provides clarification in some cases.

The results of fine-needle biopsy of the thyroid gland can be summarized as follows:

False-negative	2% to 4%
False-positive	0% to 3%
Inadequate	3% to 11%
Indeterminate	17% to 30%
Carcinoma in indeterminate cases	20% to 60%

Complications from fine-needle aspiration biopsy are negligible and consist primarily of minor bleeding. Injury to adjacent structures and more serious bleeding rarely occur after the use of larger needles. The frequency of these complications is related to the skill and experience of a physician and the location of a lesion. Seeding of neoplastic cells has been reported to be extremely rare and restricted to the use of large needles.

Needle biopsy is cost effective compared with other diagnostic studies and management plans for thyroid nodules. Its capacity for selectivity of treatment frequently results in twice the frequency of thyroid carcinoma in patients undergoing surgical procedures for thyroid nodules in practices using needle biopsy compared with previous experience when the procedure was not utilized.

Needle biopsy of the thyroid gland must be used as only one important tool. An operation is recommended for cases in which the study results are positive, indeterminate or inadequate with other factors supporting a surgical procedure, and for cases of large benign solid thyroid nodules. Needle biopsy findings are significant in preoperative discussions with patients and in directing the extent of the operative procedure. For benign cases, medical follow-up and periodic repeat biopsy are justified.

Melvin A. Block, M.D.
La Jolla, California

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Use of Computed Tomography in Cases of Blunt Abdominal Trauma

There has always been a need for a sensitive discriminating means of diagnosing intraperitoneal and retroperitoneal injury following blunt trauma. The primary need for such a diagnostic test is to avoid missing an injury, which can often be fatal or result in serious disability. This is particularly true in a shocked or unconscious patient. A secondary need is to avoid laparotomy if there is minor, insignificant or absence of injury. It is far better to err on the side of laparotomy than not, however. I know of no patient who died from diagnostic laparotomy for blunt trauma, but I do know of several instances wherein a patient died because laparotomy was not done.

For the past 15 years, the mainstay of diagnosis in a stable trauma patient with a possible abdominal injury has been peritoneal lavage. It is relatively easy to do and is fairly specific and sensitive. Its disadvantages are that it does not identify retroperitoneal injuries and, in some instances, it may be too sensitive. For example, the results may be "positive" with relatively minor liver injuries. Nevertheless, peritoneal lavage is still widely used and is still the diagnostic study of choice in many centers.

Computed tomography (CT) has advantages over peritoneal lavage in that it is both qualitative and quantitative. CT shows specific organ injury and quantitates relative blood loss, thus allowing a surgeon to use judgment on the need for laparotomy. In addition, CT is capable of diagnosing retroperitoneal injuries, specifically those involving the pancreas, duodenum and kidneys. Injuries to the diaphragm, small bowel and colon can be detected by both CT and peritoneal lavage, but both tests can also miss these injuries.

There are certain caveats and disadvantages with CT. Optimally, CT of the abdomen for blunt trauma should be done with a relatively recent generation CT scanner because of the improved resolution. In addition, double contrast, with media given by mouth and by vein, will enhance diagnosis. Interpretation requires a senior radiologist; in our institution, the radiology residents and surgeons miss 15% of injuries. CT should *not* be done on an unstable trauma patient. Like peritoneal lavage, CT should not be overused or abused. It should not be done in a case of obvious blunt abdominal trauma nor as a substitute for a thorough clinical examination by a general surgeon. Finally, CT may be slightly more expensive than peritoneal lavage, but because of the oversensitivity of peritoneal lavage, this is probably offset by reducing the need for laparotomy.

In summary, CT represents a new diagnostic method for evaluating intraperitoneal and retroperitoneal injuries. It is both specific and sensitive. I anticipate the introduction of newer imaging modalities in the near future for evaluating cases of blunt abdominal trauma. For the present, however, CT represents the state of the art.

Donald Trunkey, M.D.
San Francisco

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Liver Transplantation

The first human liver transplant was carried out by Thomas Starzl, M.D., in 1963. The initial liver transplant procedures done on the West Coast were done in the late 1960's at University of California medical centers by Fonkalsrud at Los Angeles and DeLorimier at San Francisco. Following these initial transplantation efforts, interest waned in the procedure. Throughout the 1970s, the world's experience in liver transplantation was limited to the isolated efforts of Starzl in the United States and Calne in England.

Since the advent of cyclosporine, considerable interest has been generated in liver transplantation. Active liver transplantation programs exist in at least 11 centers in the U.S., and a similar number in Europe and Asia. In the West, active liver transplant programs now exist at the University of California, Davis, in Sacramento, at UCLA and in Phoenix.

One-year patient survival rates in the precyclosporine era were from 30% to 40%. Since the advent of cyclosporine, one-year patient survival rates of between 50% and 75% have been reported. At present, the highest survival rate occurs in the pediatric population in which biliary atresia is the most common indication. It is now clear that mortality is also related to the degree of hepatic, renal and pulmonary failure present at the time of transplantation.

The most common indications for hepatic transplantation in adults include nonalcoholic cirrhosis, primary liver cancer, primary biliary cirrhosis and sclerosing cholangitis. Common indications in children include biliary atresia, α_1-antitrypsin deficiency and inborn errors of metabolism. At present, the guidelines for the timing of hepatic transplantation are poorly defined and vary widely depending on an individual patient and the diagnosis.

The resources and institutional support required for a successful liver transplantation program are considerable. An institution that initiates a liver transplant program must make a major commitment to its support. In addition, liver transplant programs must have physicians who are experienced in hepatic transplantation and who are expert in the fields of hepatology, pediatrics, intensive care, infectious disease, pathology, anesthesiology and immunology. Of particular importance is the role of the blood bank and the availability of social and psychiatric services.

Hepatic transplantation programs should be initiated under the guidance of a supervisory committee consisting of both medical and lay persons with expertise in the fields of hepatology, transplantation and ethics. This committee should review each candidate before transplantation and also review the quality of health care delivery.

Funding resources have been a continuing problem in liver transplantation. The estimated cost of a liver transplantation and initial hospital care is approximately $125,000, with an estimated cost of $25,000 a year after the initial hospital admission.

Liver transplantation represents a viable new means for treating patients with end-stage liver disease. For the foreseeable future, liver transplantation efforts will be limited to a small number of institutions that are willing to meet the tremendous resource commitment that is required to achieve optimal success levels. As limited numbers of hepatic transplantation programs will exist, patients will continue to be referred from a large geographic area, and local physicians will continue to become increasingly involved in their preoperative and postoperative care.

Richard E. Ward, M.D.
E. Steve Woodle, M.D.
Sacramento, California

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Surgical Treatment of Morbid Obesity

Morbid obesity is a disease that leads to many other diseases associated with a compromised way of life, longevity and mortality. There is no drug therapy or medical regimen that is recognized as a standard therapy for its successful treatment. The surgical procedures presently in vogue involve reducing or restricting the gastric reservoir. Intestinal bypass has proved unsatisfactory because of its long-term failure rate and high association of untoward side effects. Various stapling techniques have evolved over the past ten years in an effort to provide an easy, satisfactory technique that will be permanent. Stapling the stomach into a small reservoir with a controlled outflow has been the aim. Success rates have been reported at higher than 85%. A long-term slow regain of weight in some patients undergoing staple procedures has been recognized. This has been due to some enlargement of the reservoir, the outlet of the stomach or pulling out of the staples.

The search for a simple, permanent surgical technique continues. Various banding techniques, with and without the use of staples, are being proposed because of dissatisfaction with the late weight gain in stapled patients. A procedure of gastric wrapping and placing of a nonabsorbable, permanent restricting sleeve around the stomach appears to have some advantages. The stomach is not penetrated, or sutured, thereby diminishing some of the early morbidities sometimes seen with the more invasive gastric techniques. The procedure is permanent and not associated with late weight gain.

With the gastic-reduction procedures, there do not appear to be the metabolic side effects that so often attended the earlier intestinal bypass procedures.

Edward A. Dainko, M.D.
San Bernardino, California

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Limb Salvage for Soft Tissue Sarcoma of the Extremities

Soft tissue sarcomas of the extremities are unusual malignant tumors. Fewer than 4,000 cases of such tumors are treated annually in the United States. Amputation has been the standard therapy. In theory, amputation should be done one joint above the anatomic region involved by the sarcoma. In practice, however, even radical amputations such as hemipelvectomy or intrascapular thoracic amputation for large proximal lesions often result in close margins. Despite these radical amputations, the local recurrence rate can be as high as 10% with amputation alone.

Early attempts to surgically treat cases of soft tissue sarcoma by less than amputation resulted in high local failure rates. Local excision or enucleation of a tumor invariably cut through microscopic areas of disease. Soft tissue sarcoma appears grossly to be encapsulated. However, this “pseudocapsule” is composed of compressed normal tissue infiltrated by malignant cells. The enucleation or local excision leaves viable tumor cells in situ and will almost always lead to local recurrence.

Excision or compartmental resection can be successful in treating some patients with soft tissue sarcoma in an extremity. The theory of compartmental resection is to remove the entire involved muscle compartment from origin to insertion. In practice, this is often difficult because sarcomas are rarely confined to one muscle group. Most tumors cross several fascial planes and the tumor’s site of origin remains obscure. Wide excision removes the tumor and a rim of normal tissue in an attempt to avoid transection of microscopic disease. Local recurrence after wide excision or compartmental resection may be as high as from 30% to 40%.

The development of radiotherapy has resulted in successful alternatives to amputation. Irradiation alone is inadequate to treat gross disease and must be combined with surgical resection to avoid dose-related complications or local recurrence. Irradiation is more likely to be effective when no gross disease remains. Resection of the tumor and postoperative radiotherapy are extremely successful for sarcomas located distal to the elbow or knee. Large, more proximal tumors cannot usually be successfully treated with resection and radiotherapy.

The addition of chemotherapy to the management of a primary tumor on an extremity has achieved local control rates at least as low as those of radical amputation. We infuse doxorubicin hydrochloride intraarterially because it is a known irradiation sensitizer. After three days of chemotherapy (total dose, 90 mg) a patient receives 3,500 rads of radiotherapy preoperatively over ten days. This rapid fractionation of radiotherapy results in few complications and is biologically equivalent to 5,000 rads. The tumor is then excised with a rim of surrounding normal tissue, liberally using frozen sections for confirmation of tumor-free margins. Wherever tumor abuts against bone, blood vessels or nerves, the respective periosteum, adventitia or perineurium is removed with the operative specimen.

Using this technique, 225 patients with soft tissue sarcoma of an extremity have been treated with a local control rate of greater than 94%. Serious complications requiring reoperation were uncommon and may be related to the dose of irradiation. Amputation is no longer the only method of therapy for soft tissue sarcoma of an extremity. Patients with soft tissue sarcomas of an extremity can be treated with a limb-preserving, multimodality approach that affords a higher local control rate than a surgical procedure alone and preserves a viable, functional extremity in 94% of cases. Additionally, survival is equivalent to that achieved with radical amputation.

Armando E. Giuliano, M.D.
Frederick R. Eilber, M.D.
Los Angeles

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Ex Vivo Renal Artery Reconstruction

This year renal failure will develop in 15,000 persons, who will then require hemodialysis. With the increasing burden of hemodialysis, there is an impetus to develop new surgical techniques to revascularize kidneys affected by complex renovascular lesions. To salvage these kidneys and maintain renal function, conventional in situ methods are not appropriate, but ex vivo repair, a new technique, permits precise microvascular repair and avoids nephrectomy. "Bench work" surgical intervention describes the sequence of temporary nephrectomy, ex vivo renal perfusion and microvascular repair.

Many indications exist for an ex vivo repair. The most common is the reconstruction of lesions that affect the primary and secondary branch of the renal arteries. The most common cause of these distal lesions is fibromuscular dysplasia. Atherosclerotic renal artery aneurysms occur at this location in the renal artery as well. Additionally, several renal arteries in a donor kidney may require an ex vivo microvascular repair before transplantation. Less frequent indications include excision of bilateral renal parenchymal tumors or a tumor in a solitary kidney, repair of renal or ureteral injuries, removal of multiple or staghorn calculi and repair of a prior renal artery reconstruction that has failed.

The kidney is approached through either a midline or a flank incision with circumferential dissection of the renal artery and vein. After they are transected, the kidney is removed from the renal fossa and placed on continuous hypothermic perfusion on a dissecting platform. A reconstruction procedure can then be done in an asanguineous field, with optimal exposure and illumination, using microvascular surgical technique. Following repair, the kidney can be replaced in either an orthotopic or a heterotopic position in the iliac fossa. Although an autogenous saphenous vein is an acceptable graft for renal artery substitution, we prefer the branched hypogastric artery because of its anatomic configuration and size, its resistance to aneurysmal degeneration or stricture and its growth when implanted in a growing child.

Although most of the surgical literature on this subject comprises case reports, we have followed for periods of six months to six years 26 patients who underwent ex vivo repairs. Of 23 reconstructions, 22 were patent as determined by postoperative angiography. In all, 95% of the hypertensive patients were cured or their conditions improved during follow-up. Late postoperative arteriograms (more than three years) showed continuing patency in all six patients studied.

The ex vivo "bench work" operation, a relatively recent addition to vascular surgical procedures, has, by preserving kidneys and their important function, provided a significant contribution for patients affected with a variety of complex lesions.

Ronald J. Stoney, M.D.
Craig Kent, M.D.
San Francisco

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Preoperative Biliary Tract Drainage

During the 1970s, numerous authors reported that percutaneous transhepatic drainage could be done with little morbidity. During this same period, surgical relief of obstruction in severely jaundiced patients was associated with postoperative morbidity in 40% to 60% and mortality in 15% to 25% of patients. For this reason, preoperative percutaneous transhepatic drainage has been recommended for these patients. Moreover, two retrospective studies from Japan and another nonrandomized analysis from Ohio State University suggested that preoperative biliary tract drainage might be helpful. Thus, on the basis of these retrospective studies, many clinicians have accepted that preoperative biliary drainage should be done routinely before surgical intervention in patients with deep jaundice. However, more recent reports from several institutions have cautioned that a significant proportion of patients undergoing this procedure are subject to both early and late complications.

Thus, controversy exists as to what role preoperative biliary drainage should play. To help answer this question, three prospective randomized studies have recently been completed. The first such study was done by Hatfield and associates from South Africa. These investigators failed to find any advantage in terms of decreased postoperative morbidity or mortality for preoperative percutaneous transhepatic drainage: 4 of 29 patients (14%) who had drainage and 4 of 28 (14%) who did not undergo drainage died. Five of the eight deaths, however, occurred in patients in whom either percutaneous transhepatic drainage could not be done (one patient) or who did not have a surgical procedure (five patients). The second study was done at the Hammersmith Hospital in London by McPherson and co-workers. In this study, of 65 patients, hospital mortality was actually higher in the drained (32%) than in the undrained (19%) patients ($P > .05$). Of 11 deaths in the drained group in this study, 5 occurred in patients who did not have an operation.

The third study was done at the UCLA Medical Center. In this study of 75 patients, hospital mortality was 8% among drained patients and only 5% in those patients who had surgical treatment without preoperative percutaneous transhepatic drainage. In both this study and the Hammersmith study, no significant differences in postoperative morbidity were noted between the drained and undrained patients. Moreover, in both of these studies the duration of hospital stay was significantly prolonged ($P < .05$) in the patients who had preoperative biliary tract drainage. Thus, although retrospective analyses suggested that preoperative percutaneous transhepatic drainage might be beneficial, prospective studies have not supported this early enthusiasm. One criticism of each of these prospective studies, however, is that the duration of preoperative drainage (10 to 18 days) may not have been sufficient to reverse the multiple metabolic and immunologic abnormalities associated with severe obstructive jaundice.

Henry A. Pitt, M.D.
Los Angeles

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Percutaneous Abscess Drainage and Related Radiologic Procedures

Percutaneous drainage procedures continue to evolve with new and innovative advances. Abscesses that previously were not considered appropriate for catheter drainage may be cured in some cases, while needle puncture of certain fluid collections and organs that had been assiduously avoided now is done safely and with clinical benefit. Progress has accrued from laboratory work, improvement in techniques and the necessity of application in desperately ill patients with no reasonable alternatives.

Unilocular (or bilocular) and relatively superficial abscesses are drained with catheters successfully in about 90% of cases. Because of superior resolution, computed tomography (CT) is used for guidance in most cases. The use of large, multihole sump systems, an adequate number of catheters and copious irrigation has now made this a routine procedure. Some hepatic abscesses, those in superficial abdominal sites, and abscesses in extremities (such as in the thigh) are drained under sonographic guidance.

Enteric-related abscesses have been drained successfully or reduced by partial drainage. Thus, appendiceal abscesses, peridiverticular abscesses, Crohn's-related abscesses and perianastomotic abscesses are amendable to percutaneous abscess drainage. Cutaneous fistula formation after catheter drainage of Crohn's disease abscesses has not been reported to date. The goal of percutaneous treatment for periappendiceal abscesses is to allow a patient's condition to "cool down" and thus to simplify the surgeon's task at a subsequent appendectomy. With enteric-related abscesses, longer term catheterization (several weeks) is often required, compared with unilocular uncomplicated abscesses (about five to ten days).

Patients with pancreatic abscesses and pancreatic pseudocysts have been treated successfully in some cases and improved in other cases. Failure of percutaneous drainage generally occurs when too few catheters are placed or they are removed too quickly. For successful pseudocyst drainage, the communication to the disrupted pancreatic duct must seal, and antegrade obstruction of the duct must resolve. Transgastric placement of catheters for percutaneous drainage has been advocated by some. Successful pancreatic abscess drainage usually requires more than one catheter because the collections are frequently multioculated; similarly, more follow-up studies (sinography, sonography and CT) are utilized for close follow-up and additional catheter maneuvering, if necessary. These are tedious, prolonged drainages but are frequently helpful in critically ill patients.

Amebic abscesses are drained in a minority of cases. Specific indications for percutaneous abscess drainage include the following: to differentiate pyogenic from amebic in an acute situation, clinical deterioration while receiving medication, initial false-negative serology, pain and imminent rupture and left lobe abscesses. Ultrasound may be used for guidance in some of these cases.

Collections in the chest that are not drained successfully by standard tube thoracostomy due to tube malpositioning may be drained by CT- or ultrasound-guided percutaneous drainage. Some of the most dramatic cures of purulent collections are achieved with catheter drainage of empyemas or infected pericardial collections. When lung abscesses do not have adequate bronchial drainage, they too may be drained by percutaneous catheters. These catheters are preferentially inserted through areas of previous pleural contamination, so as not to spread infection to uninvolved pleura.

Drainage of hematomas, lymphoceles and benign cysts has also been accomplished percutaneously. Each of these is complicated by various specific problems: hematomas are quite thick, lymphoceles tend to recur due to leakage of small lymphatics and cysts may recur due to persistent mucosal secretion. The last may be sclerosed in some cases through the percutaneous catheters.

Percutaneous radiologic-guided puncture of the stomach for feeding or decompression is an outgrowth of percutaneous drainage techniques. It is done under fluoroscopy, with pre-procedure location of the transverse colon and sonographic identification of the left lobe of the liver to avoid inadvertent puncture. Catheters are placed directly into the stomach after insertion of a nasogastric tube and inflation of the stomach with either an intragastric balloon, fluid or air. Catheters may be placed either into the stomach or through the stomach into the small bowel for more distal feeding or decompression.

Percutaneous puncture of the gallbladder is used for biliary tract decompression for malignant obstruction, temporizing cholecystostomy for cholecystitis and empyema of the gallbladder or as an access for stone removal. *Echinoccus* cysts, once considered taboo to puncture, have now been reported to have undergone successful percutaneous drainage. The *Echinococcus multilocularis* cyst apparently can be punctured safely, whereas the *Echinococcus alveolaris* type has associated anaphylactic risk.

Eric vanSonnenberg, M.D.
San Diego

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Anal Sphincter-Saving Operations

Selected cases of rectal cancer, chronic ulcerative colitis and colonic polyposis may be treated today with sphincter-preserving operations. In the past, many of these patients would have had complete excision of the rectum with a permanent ileostomy or colostomy. Enthusiasm and interest in new techniques for sphincter preservation arise from a better understanding of the various diseases, an improved appreciation of sphincter physiology and the continued desire of patients and physicians to preserve sphincter function, thereby avoiding a permanent stoma.

Rectal cancer involving the upper third of the rectum is conventionally treated with a low anterior resection with anastomosis. However, tumors involving the middle and lower thirds of the rectum have more often been treated by abdominoperineal excision of the rectum. Extended low anterior resection is today done for many of these tumors in the lower rectum provided an adequate margin distal to the tumor can be obtained (2 to 5 cm). Wide excision of the surrounding tissues and retrorectal lymphatics is important to achieve local control.

The development of new intraluminal stapling devices has aided technically in carrying out low rectal anastomosis or coloanal anastomosis done transanally. A temporary diverting colostomy may accompany these low restorative resections to protect the patient if an anastomotic leak should occur. In addition, cancers involving the lower third of the rectum may be selectively approached transanally by excising locally or fulgurating. Criteria for this approach include tumors that are exophytic, well differentiated, mobile and of relatively small size. Caution in these approaches must be stressed in order not to sacrifice principles of adequate cancer surgical treatment, thereby risking local recurrence. To date, results of sphincter-saving procedures for rectal cancer that include wide excisional pelvic dissection and intraluminal washout appear to compare favorably with those of total rectal excision.

Severe inflammatory changes (chronic ulcerative colitis) or extensive polyposis of the rectum (familial polyposis) often preclude an ileorectostomy after removing the abdominal colon. Because both diseases involve only the mucosa of bowel (compared with Crohn's transmural disease), recent trends include removing or stripping the mucosa of the rectum, leaving the muscular tube of bowel with intact nerves—thereby preserving the sphincter. Mucosal stripping of the rectum is done by entering the submucosal plane at the anorectal junction and removing mucosa of the lower rectum. Following abdominal colectomy, a pouch of terminal ileum is constructed to allow distensibility and reservoir capacity. The pouch may be constructed using several proven techniques such as the "J" pouch (Utsunomiya), "S" pouch (Parks) or side-to-side isoperistaltic pouch (Fonkalsrud). The pouch is advanced through the rectum, which is devoid of mucosa, and sutured to the anus. A temporary diverting ileostomy is done concomitantly to allow for healing of this anastomosis. Incorporating an ileal pouch and reservoir improves the functional results in a significant number of patients who undergo this type of operation with sphincter preservation.

Sphincter-saving operations for rectal cancer, chronic ulcerative colitis and familial polyposis improve the lifestyle for selected patients. Careful screening of patients in the preoperative period and careful postoperative evaluation and scrutiny are necessary to further determine the future role of these operative approaches.

Thomas R. Russell, M.D.
San Francisco

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Splenic Salvage

Splenic salvage is the preservation of all or part of the spleen as a planned surgical procedure, in contrast to total splenectomy. Until less than a decade ago, this approach was not only deemed heretical but was rarely practised anywhere in the world. Today it is widely accepted and done everywhere.

The impetus for splenic salvage was provided by the finding that the spleen plays an important role in the immunologic defense against sepsis, particularly infections caused by encapsulated organisms such as the pneumococcus and meningococcus.

The techniques of topical hemostasis for superficial splenic injuries and splenorrhaphy or partial splenectomy for more severe injuries have been well described in numerous reports. With these techniques, splenic preservation has been shown to be not only feasible but safe when used with judgment and care. Techniques using splenic fragments as omental implants are of debatable efficacy in maintaining immunologic competence and require further evaluation.

Although the major application of the concept of splenic salvage has been in splenic trauma, conservative splenic operations have also been described for splenic cysts and cases of Gaucher's disease.

The nonoperative management of splenic injuries has been a standard of practise in the selective management of splenic injuries in children, who are at high risk for overwhelming postsplenectomy sepsis. Recent reports describe the same mode of management used successfully in highly selected adult patients with known splenic injuries, if careful clinical observation indicates that bleeding from the injured spleen has ceased.

Leon Morgenstern, M.D.
Los Angeles

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Conservative Surgical Treatment of Carcinoma of the Breast

Surgical treatment of primary carcinoma of the breast has changed significantly in the United States in the past decade. The radical mastectomy first gave way to the modified radical mastectomy as the surgical standard of care. Abroad, wide surgical ablation therapy has not been widely practiced. Proof by our foreign colleagues of the efficacy of conservative surgical treatment of primary breast carcinoma *coupled with* radiation therapy seems to be having an effect on surgical practice in this country.

Prospective randomized clinical trials abroad have shown the efficacy of breast conservation operation and radiation therapy in the local control of the disease with apparent long-term survival equivalent to that of regional excisional therapy. The foreign studies have shown local recurrence rates in the range of 5% at five years for nonmastectomy-treated patients. In retrospective studies, local recurrence rates during the sixth to tenth year following partial mastectomy and irradiation approach those of the first five years; thus, by ten years local recurrence rates are in the range of 12% to 14%. In the United States, early results of the National Surgical Adjuvant Breast Project have confirmed the findings of foreign studies. The final results of that study will be required, however, to show equivalent long-term survival in conservatively treated patients.

The effect of these studies on surgical practice in the U.S. is beginning to be documented. A national survey has recorded the disappearance of the Halsted radical mastectomy, the increasing use of modified radical mastectomy and a threefold increase in the use of partial mastectomy between 1976 and 1981. Since 1981 the geometric increase in the use of partial mastectomy continues and appears to be resulting in a decreasing use of the total mastectomy therapy.

Attempts to standardize the surgical approach to breast conservation are beginning to be reported. Many questions concerning the technical details of conservative surgical treatment continue to be addressed. These include the exact handling of the primary tumor, the extent of resection of breast necessary and the extent of axillary dissection necessary to insure adequate staging of disease. The technical factors involved in radiation therapy also are being addressed but are unsettled. However, nonmastectomy treatment coupled with radiation therapy for stages I and II carcinoma of the breast has established itself as a therapeutic option readily available to American women. Breast cancer continues to be a disease requiring multimodal therapy from the time of diagnosis.

John J. Coyle, M.D.
La Jolla, California

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Variations in Medical Practice and Hospital Costs

JOHN E. WENNBERG, M.D.

I am very pleased to be asked to testify on the topic of variations in medical practice. My research into geographic patterns of health care delivery reveals extensive variation in the use of hospital services from one community to another. The extent of variation in reimbursements to hospitals under the Medicare program is such that if the low cost patterns of care were the norm, we would not be faced with the pending bankruptcy of the Medicare Trust Fund nor would we be now concerned with the spectre that medical care must be rationed. For many medical or surgical conditions, the variations suggest opportunities to reduce expenditures under the Medicare and Medicaid programs without reducing the benefits of medical care. For other conditions, the variations reveal a critical need to evaluate the outcomes of different approaches to treatment, so that patients and physicians may better understand the significance of their choices in using medical care. Before concluding my testimony, I will describe a plan to address the cost containment and outcome assessment imperatives revealed by the variations and make some specific suggestions as to how the Department of Health and Human Services can contribute.

JOHN E. WENNBERG, M.D., Professor of Epidemiology, Department of Community and Family Medicine, Dartmouth Medical School, Hanover, New Hampshire. This article constitutes Dr. Wennberg's testimony to the Subcommittee on Labor, Health and Human Services and Education of the U.S. Senate Committee on Appropriations.

Table 1

The Quantity Of Hospital Resources Expended On The Populations Of New Haven, Connecticut And Boston, Massachusetts By Hospitals Providing Resources (1978)

Hospital	Percent of admissions from the local pop.	Beds allocated to local population	Market share	Per Capita Rates[b]		
				Beds	Expend.[a]	Personnel
New Haven, Connecticut (pop. est. 372,900)						
Yale-New Haven Univ. Hosp.	68.3	541.6	54.8	1.5	124	5.5
St. Raphael	86.4	416.6	38.1	1.1	82	3.5
Out-of-area hospital	–	65.0	7.1	0.1	9	0.5
All hospitals	–	1023.2	100.0	2.7	215	9.5
Boston, Massachusetts (pop. est. 732,400)						
Boston teaching hospital (N=7)	42.6	1828.0	59.0	2.5	322	13.1
Boston community hospital (N=11)	50.6	843.0	23.3	1.2	84	3.3
Out-of-area hospital	–	524.4	16.7	.7	42	1.8
All hospitals	–	3195.4	100.0	4.4	448	18.2

Note: The estimates for the resources allocated to the New Haven and the Boston populations are made by multiplying the amount of resources provided by each hospital by the percent of admissions that are from the local population (column 2). For example, 542 of the Yale-New Haven University Hospital's total complement of 793 beds are used by the residents of New Haven. The estimate for the total numbers of beds is obtained by summing column 3 which, it will be noted, includes beds from out-of-area hospitals that provided services to the population of New Haven. For comparative purposes, we are particularly interested in per capita rates. The exhibit shows these for beds, numbers of personnel, and inpatient expenditures. All rates are corrected for boundary crossing.

[a] For inpatient services.

[b] Beds and personnel per 1,000 population, expenditures per person.

The Practice Variation Phenomenon

The practice variation phenomenon first came to my attention some fifteen years ago, when my colleagues and I implemented a system for monitoring health care delivery among hospital markets in Vermont. A unique feature of our approach is that we can identify the amount of care consumed by individuals in a specific population and are thus able to calculate rates per capita. We noticed that the per capita expenditures for hospitalization in some areas were more than double those of others, even though studies of the populations of Vermont communities showed that the patients were quite similar and differed little in terms of medical need. We repeated these studies throughout New England and found similar patterns of variation in each state. These variations are not explained by differences in population characteristics and there seems to be no clear association between the factors that one ordinarily thinks should contribute to high costs, such as a greater percentage of the elderly in the population or the presence of a teaching hospital. However, differences in hospital costs do closely follow the distribution of hospital beds and numbers of persons employed in the hospital industry. (See Table 1)

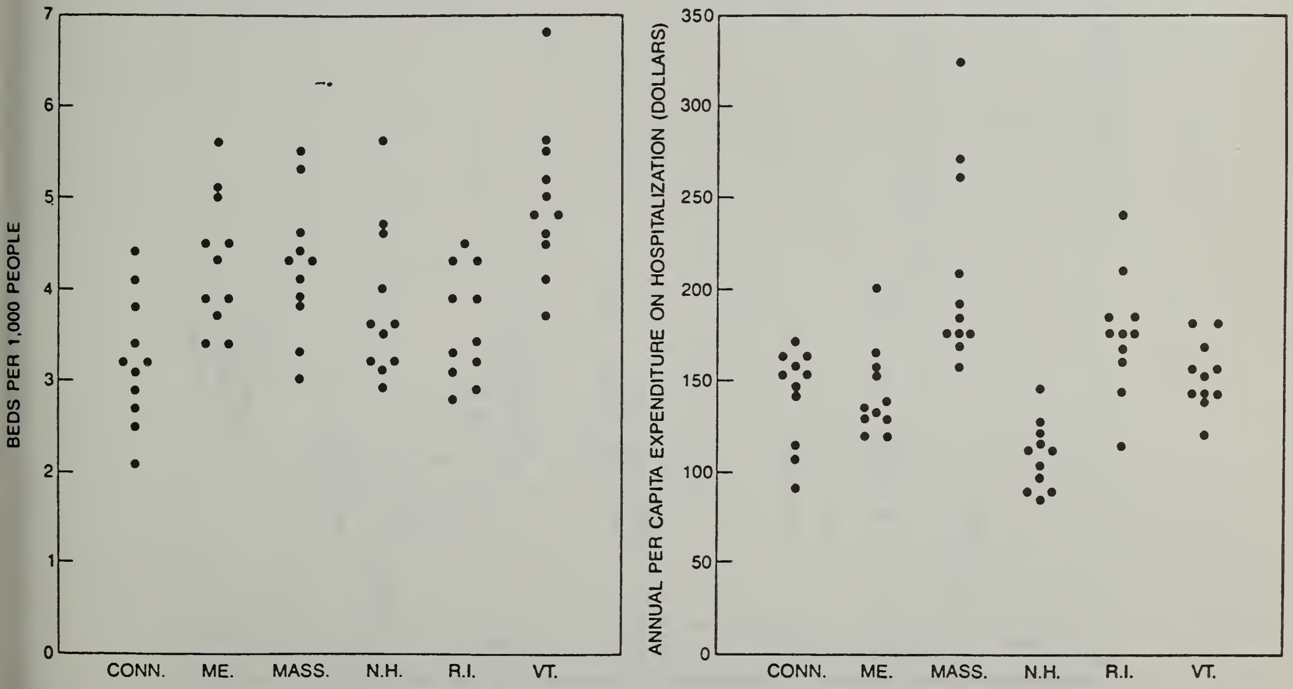
Let me give some examples. We found that hospital costs in Boston are about twice those of New Haven, even though most resident hospitalizations in each of these communities is to a teaching hospital and the percent of the population over sixty five is about equal. Boston had about 4.4 beds and, in 1978, about 18.2 employees per 1,000 residents while New Haven had about 2.7 beds and 9.5 employees. For 1982, we found that reimbursements for hospitalization of the elderly were 74 percent higher in Boston than in New Haven. If hospital insurance reimbursements for 78,000 Medicare enrollees living in Boston were the same as in New Haven, the outlays from the trust fund would have been $85 million rather than the actual $148 million, a savings to the trust fund of $63 million.

Exhibit 1 summarizes the extent of variation in expenditures and hospital bed allocations we have observed in our New England studies.

These differences in the per capita rates of use of resources are not intuitively known by the doctors or the patients on the scene. They become apparent only when they are measured directly. For example, I have asked clinicians who practice in both Yale and Harvard teaching hospitals to estimate the per capita expenditures for hospitals in each market. Their answers indicate they have no awareness of the magnitude of the difference; what is more surprising, many do not accurately guess which of the two markets is more expensive.

In my research, I have been very interested in how hospital resources are used—the specific services the

Exhibit 1

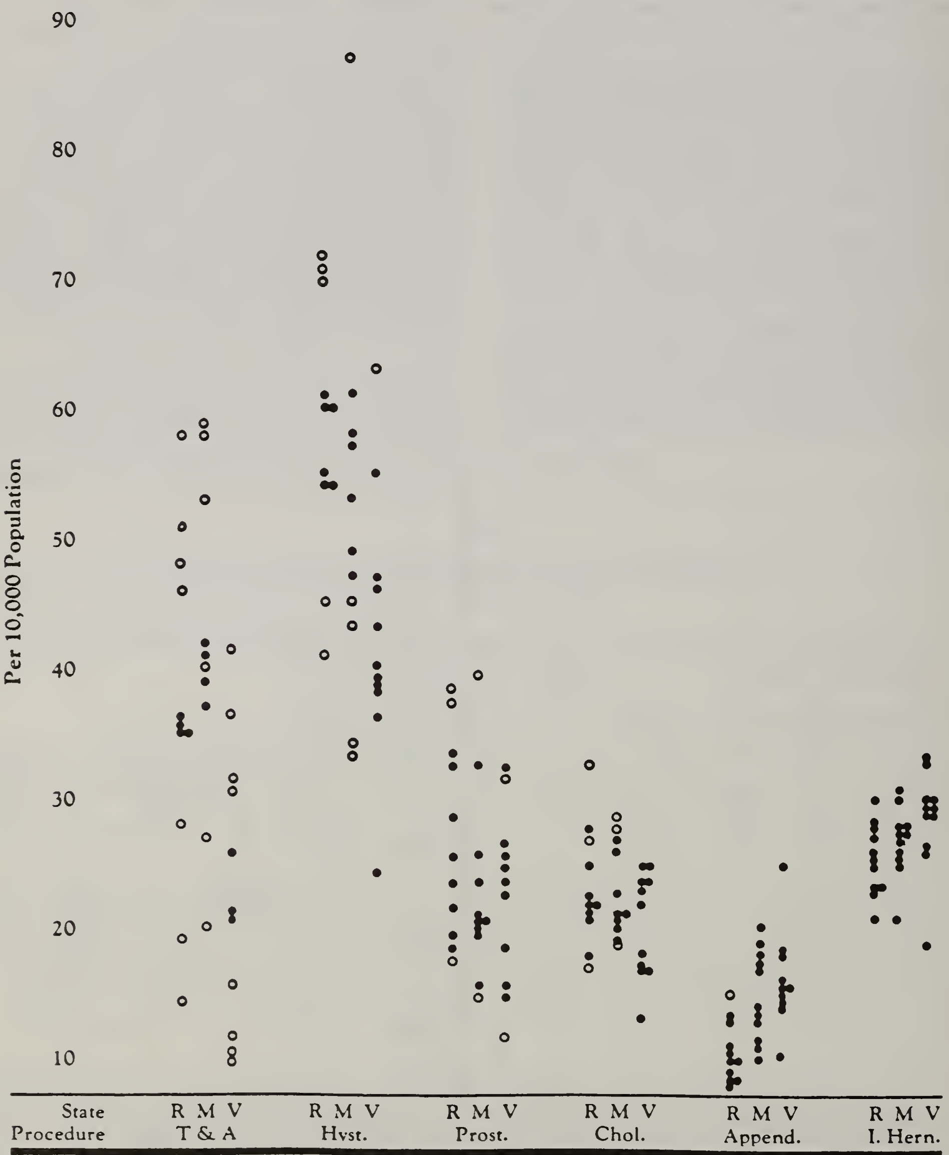


NUMBER OF HOSPITAL BEDS per capita and the annual amount spent per capita on hospital treatment also show the influence of geographic variations in medical care. The data are for the 11 most populous hospital areas in each of the six New England states. The number of hospital beds per 1,000 people (adjusted for the number of people who leave their hospital area for treatment) ranges from about two to more than six. The ratios thus range from well below to well above the four beds per 1,000 established by the Federal Health Planning Program as a standard. Furthermore, the variation in each state is so great that the number of beds per capita in the state or county as a whole (a measure often employed by health-planning agencies) bears little relation to the conditions prevailing in each community. The average amount spent on treatment in hospitals in 1975 ranged from less than $100 per capita to more than $300 in the 66 areas.

dollars, facilities and manpower produce. Here the findings are clear and consistent. Some causes of hospitalization show very little variation in admission rates among hospital markets, no matter what the level of resource investment. Examples of low variation admissions include hospitalizations for fractures of the hip, acute myocardial infarction (heart attack), strokes, appendectomy and inguinal hernia repair. But these are the exceptions. Most causes of admission are highly variable, including many common surgical procedures. For example, we have found that the rates for tonsillectomy have varied as much as eightfold: nearly 70 percent of children had their tonsils removed by age 15 in one area, while in the low rate community fewer

Exhibit 2

Age-Adjusted Rate Of Procedure For Six Common Surgical Procedures In Rhode Island, Maine, and Vermont (1975)



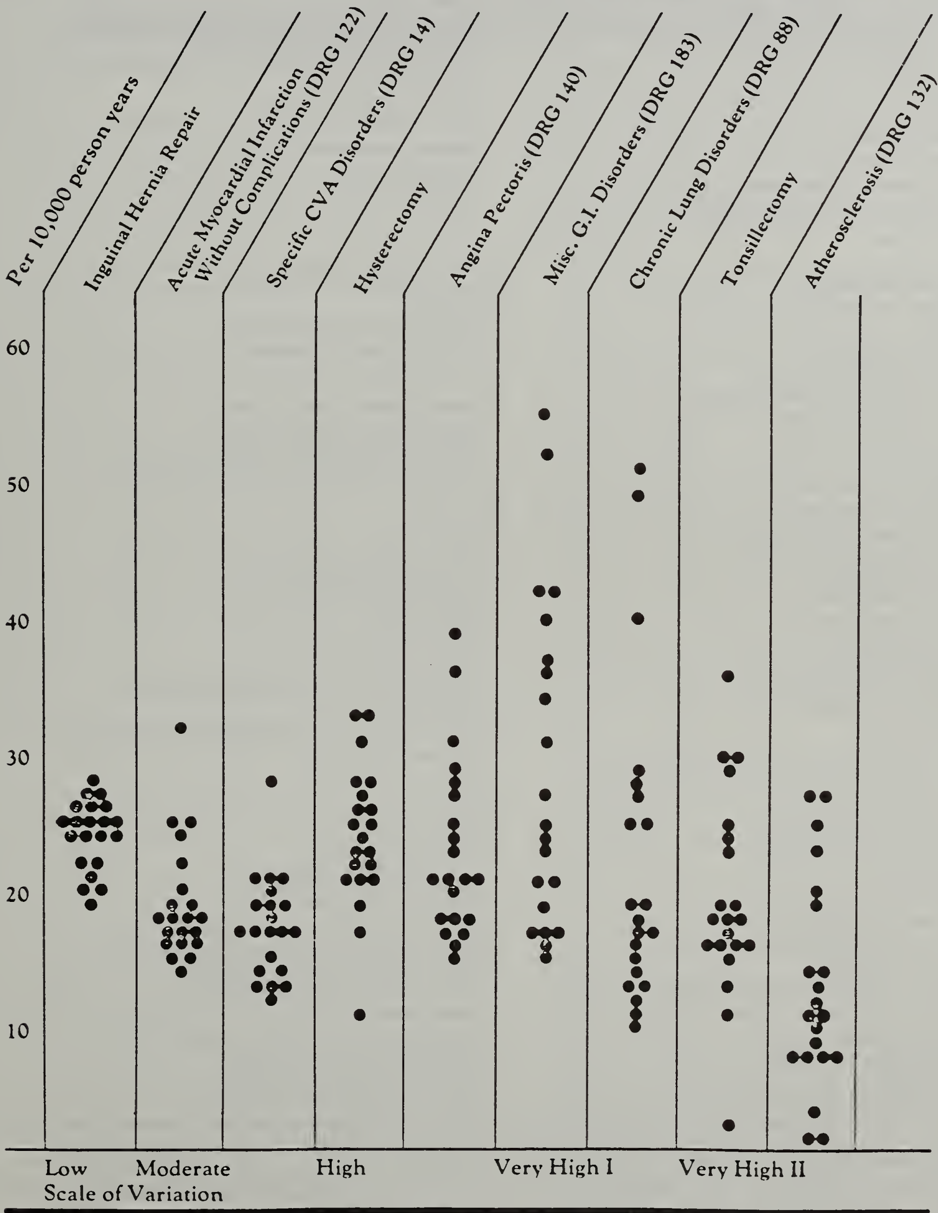
Note: Rates of surgical procedures vary greatly among hospital areas. The rates shown are for the six most common surgical procedures for the repair or removal of an organ in the eleven most populous hospital areas of Maine, Rhode Island, and Vermont (1975). The rate of tonsillectomy varies about sixfold among the thirty-three areas; the rates of hysterectomy and prostatectomy vary about fourfold. Moreover, many of the extreme rates for these procedures differ from the average rate for the state by an amount that is statistically significant (open circles). There is much disagreement among physicians on the value of the high-variation procedures. Similar patterns of variation for these procedures have been observed in Iowa, England, and Norway. R = Rhode Island; M = Maine; V = Vermont.

than 8 percent experienced the operation. The probability of having a hysterectomy has varied from less than 15 percent to well over 60 percent of women by age 75, depending on place of residence. And the chances that a male will have a prostatectomy by age 75 have ranged from a low of about 15 percent to well over 50 percent in different hospital market areas.

Exhibit 2 shows the typical patterns of variation seen for common surgical procedures.

Exhibit 3

Age-Adjusted Incidence Of Hospitalization (1980-82)
For Selected Medical DRGs And Three Common Surgical Procedures
For Maine Hospital Markets



Note: The DRGs with similar statewide rates were selected to demonstrate the spectrum of variation in the incidence of DRG-specific hospitalizations among Maine hospital markets. Each circle represents a hospital market area. The graph is limited to markets with 45,000 person years or greater. The incidence of hospitalization for most DRGs is more variable than for hysterectomy.

The variation phenomenon has been similarly documented in Europe and is not limited to health delivery systems based on fee-for-service financing. I have found the pattern of variation for common surgical procedures consistent among fee-for-service hospital markets in Iowa, Maine, Massachusetts, Rhode Island, and Vermont; among health maintenance organizations in the United States and among health care regions in Canada, England and Norway, even though obvious differences exist in the supply of hospital beds and surgeons, the organization and financing of services, and in the cultural and demographic characteristics of the residents.

Our more recent studies have been concerned with variations in hospitalization rates among medical as well as surgical admissions. We have found that *most* causes of admission as classified by Diagnosis Related Groups (DRGs) have highly variable admission rates. Indeed, nearly 90 percent of all non-obstetrical cases admitted to

Exhibit 4

Medical And Surgical Causes of Admissions Ranked In Ascending Order Of Variation In Incidence Of Hospitalization (1980-1982)

Medical Causes of Admission

Low Variation
- None

Moderate Variation
- Acute myocardial infarction
- Gastro-intestinal hemorrhage
- Specific cerebrovascular disorders

High Variation
- Nutrional and metabolic diseases
- Syncope and collapse
- Respiratory neoplasms
- Cellulitis
- Urinary tract stones
- Cardiac arrhythmias
- Miscellaneous injuries to extremities
- Angina pectoris
- Toxic effects of drugs
- Psychosis
- Heart failure and shock
- Seizures and headaches
- Adult simple pneumonias
- Respiratory signs and symptoms
- Depressive neurosis
- Medical back problems
- Digestive malignancy
- G.I. obstruction
- Adult gastro-enteritis
- Peripheral vascular disorders
- Red blood cell disorders
- Adult diabetes
- Circulatory disorders exc. AMI, with card cath.

Very High Variation
- Deep vein thrombophlebitis
- Adult bronchitis and asthma
- Organic mental syndromes
- Chest pain
- Transcient ischemic attacks
- Kidney and urinary tract infections
- Acute adjustment reaction
- Minor skin disorders
- Trauma to skin, subcut. tiss. and breast
- Chronic obstructive lung disease
- Hypertension
- Adult otitis media and URI
- Peptic ulcer
- Disorders of the biliary tract

Medical Causes of Admission (cont.)
- Pediatric gastro-enteritis
- Pediatric bronchitis and asthma
- Atherosclerosis
- Pediatric otitis media and URI
- Pediatric pneumonia
- Chemotherapy

Surgical Causes of Admission

Low Variation
- Inguinal and femoral hernia repair
- Hip repair except joint replacement

Moderate Variation
- Appendicitis with appendectomy
- Major small and large bowel surgery
- Gall bladder disease with cholecystectomy
- Adult hernia repairs except inguinal and femoral

High Variation
- Hysterectomy
- Major cardiovascular operations
- Pediatric hernia operations
- Hand operations except ganglion
- Foot operations
- Lens operations
- Major joint operations
- Stomach, esophageal, and duodenal operations
- Anal operations
- Female reproductive system reconstructive operations
- Back and neck operations
- Soft tissue operations

Very High Variation
- Knee operations
- Transurethral operations
- Uterus and andenexa operations
- Extra-ocular operations
- Misc. ear, nose, and throat operations
- Breast biopsy and local excision for nonmalignancy
- D & C, conization except for malignancy
- T & A operations except for tonsillectomy
- Tonsillectomy
- Female laparoscopic operations except for sterilization
- Dental extractions and restorations
- Laparoscopic tubal interruptions
- Tubal interruption for nonmalignancy

[a] Causes of hospitalizations are taken from Diagnostic-Related Disease Classification system but cases have been grouped without regard to presence or absence of significant complication. Obstetrical and neo-natal causes of hospitalization are excluded. Ranking is according to the Systematic Component of Variation. Variations are measured across thirty hospital markets. The exhibit lists individually only those with more than 1,500 cases. More than 50 percent of hospitalizations are represented in the exhibit. Classes of variation are defined such that the variation associated with the first entry in a class is significantly more variable than the first entry in the previous class. For additional information see K. McPherson, J.E. Wennberg, O.B. Hovind, and P. Clifford, *The New England Journal of Medicine* 307 (1982):1310-4.

hospital have greater variation than hysterectomy.

The pattern of variation typical for medical DRGs is shown in Exhibits 3 and 4.

Why is it that such differences exist in the way medicine is practiced?

One reason is that for many common conditions, the necessary scientific studies that allow physicians to define the optimum treatment have not been done. Rather than consensus, there is controversy and disagreement among clinicians on what constitutes the best treatment for a particular problem. This is often the case when the clinical choice involves a medical versus a surgical approach to a given illness. The controversies arise because the natural history of the untreated or conservatively treated case is poorly understood and well designed clinical trials are notably absent.

Examples include surgical versus non-surgical treatment for menopausal symptoms, for moderate urinary tract obstruction due to benign hyperplasia of the prostate, for recurrent sore throats related to hypertrophy of the tonsil, and for coronary by-pass surgery following myocardial infarction. Well-defined scientific norms simply do not exist to delimit the practice options physicians select to treat these maladies. As a consequence, the opinions of individual doctors can vary substantially, based upon their subjective experience. Because many of the conditions are extremely common, eventually affecting most if not all people to some degree, the candidates that could qualify for operative intervention sometimes appear upwardly limited only by the size of the population.

Examples of such conditions that are particularly important for the Medicare program include prostatic hypertrophy, cataracts, and coronary artery disease. The public interest would be served by better understanding the implications of the variations, particularly the quality of life gains that follow the use of surgical approaches as compared to more conservative treatments. This should be a compelling priority for operations that carry a high surgical mortality rate. One such operation is prostatectomy, where the post-operative mortality rate during hospitalization is about one percent or slightly higher. We calculated that if the conservative or low rate practice style seen in our New England studies were the national norm, one should expect about 1,900 deaths per annum in the United States following this operation. But if the national norm were the high rate, the number would be about 6,800. The responsibility for further research into the outcome implications for this procedure seems to rest at least in part with the federal government since many of its activities promote the public's use of care and, for this procedure, most of the operations done in the United States are financed by the Medicare program.

There are other important reasons for variations that do not rest on scientific controversies and these provide the best opportunities for immediate savings on the cost of hospitalization. Physicians in some hospital markets practice medicine in ways that have extremely adverse implications for cost because they use the hospital for treating relatively minor illnesses or for performing minor surgery much more often than do most of their colleagues. The professional reasons that lead to a particular practice style are likely to be complex and idiosyncratic—involving matters of professional or patient convenience, inexperience or insecurity on the part of clinicians, individualistic interpretations of the requirement for "defensive medicine," and unexamined viewpoints about the relative risks associated with ambulatory versus inpatient treatment. To one degree or another, most of the medical causes of admission appear to fall into this class as do most minor surgical procedures. Common examples include admissions for virtually all pediatric medical diagnoses, and minor surgery such as a cystoscopy, teeth extractions, sterilization, or breast biopsy. These examples typically exhibit more than a tenfold variation in admission rates among hospital markets. Among the Medicare populations, the common examples include gastro-enteritis, chronic obstructive lung disease, atherosclerosis, bronchitis and asthma, and simple pneumonias.

The consequences for costs of practice styles that favor inpatient over ambulatory settings are large, indeed. Take as the first example the differences in pediatric medical hospitalization rates, which are reflective of the variations that may be expected under Medicaid's program for dependent children. In Maine, a state with about one million residents, the largest hospital market area had utilization rates only 55 percent of the state average over the three-year period of our study. Based on an estimated cost per case of $1,300, we can project a net saving of about $2.5 million in this hospital market over average costs. If the practice style seen in this area were emulated throughout the state, the costs of pediatric medical hospitalizations in Maine during the first three years of this decade would have been about $15.5 million, rather than the estimated $28.3 million—a saving of $12.8 million.

As a second example, consider medical admissions for the population over age sixty-five, that is, those eligible for Medicare. One of the three most populous hospital markets in Iowa hospitalizes the elderly for medical admissions at a rate that is only 66 percent of the state average. Assuming an average cost per case of $2,000, we can estimate a net saving there of $2.2 million for Medicare medical admission in 1980. If the hospitalization rate for this area were the norm for the state, the bill for medical admissions for the 190,000 persons over sixty-five years of age in our study would have been $72 million rather than the estimated $109 million—a saving of $36 million in one year alone.

Let me place these estimates of potential savings in a slightly different context. One hears a lot these days about how the cost crisis is leading to the need to ration medical services. This fear seems to me to be misplaced. The problem is that we are uninformed about the opportunities for reallocating existing resources. If the more conservative, ambulatory-oriented practice styles were to become the norm—and if hospital administrators and trustees translated the decrease in demand for specific services into a reduction in the capacity of the hospital system—then substantial cost savings would follow. Indeed, the resources that can be saved through the more judicious use of hospitals should more than meet the demands for investment in effective new technologies, such as liver transplants, for some time to come.

A Plan for Action

What needs to be done?

Let me state at the outset that the goal is emphatically *not* to obliterate all variations in the practice of medicine nor to reduce the practice of medicine to a cookbook. Obviously, physicians must have freedom to apply their skills as they and their patients see fit. Medicine is as much art as it is science and will always be so. An enterprise as large as medical care will always produce variations in approach. Rather, the goal should be to reduce variations that are highly aberrant, that reflect supply factors rather than scientific knowledge or that reflect idiosyncrasies of physicians rather than the values, needs, or wants of their patients.

In the summer 1984 edition of *Health Affairs,* I suggested a three-part plan for dealing with the practice variation phenomenon in a way that improves health care outcomes and promotes cost-containment. I would like to review the outline of this plan and suggest steps the federal government could take to ameliorate the problems.

Monitoring Performance in Hospital Markets

The first part calls for a closer monitoring of medical practice in local markets, using epidemiologic techniques to create reports giving the numbers per capita of hospital beds, employees and expenditures as well as the rates of use of services and their outcomes. These reports provide an objective means for identifying variations, for assessing practice patterns and for planning corrective actions. Without them, people are simply unaware of what is going on. The reports should be made available routinely to practicing physicians, to state and county medical associations, to Professional Review Organizations (PROs), to hospital administrators, and to others with interest in the measurement of hospital performance. (An excerpt from *Health Affairs,* including examples of these reports, is included as an appendix to this testimony.)

The data necessary to create the reports are, for the most part, generated already as part of the routine management of health insurance or regulatory programs and are contained in Medicare, Medicaid and Blue Cross/Blue Shield claims systems and in hospital discharge abstracts similar to those used in the DRG program. Because of its national coverage and the richness of its database, the Medicare program offers the best immediate opportunity to implement feedback in all parts of the country. The federal government now requires each hospital to record uniform information on the costs, reasons for hospitalization and treatments for each hospitalization paid for under the Medicare program. When this information is linked to claims-data under the Medicare part B program and to patient registration files, a registry is created of the medical care events and certain outcomes for virtually the entire population of the United States who are sixty-five years and older. The many problems for public policy concerning the equity and outcome of care that are illustrated by the variation phenomena, as well as the federal government's own need for effective cost containment, lead me to recommend that this very important national resource be used for this purpose.

Dealing with the Cost-Containment Problem

The second aspect of my plan calls for the use of the reports in a strategy to reduce the use of hospitals for highly variable medical admissions and minor surgery which can be treated effectively and safely in the ambulatory setting. The feedback reports give the information necessary for action: they identify the hospital market areas with costly practice styles for specific discretionary admissions and costly administrative practices with regard to hospital expenditure, bed, and personnel rates. The shift of such patients to the ambulatory setting will neither disrupt the patient-physician relationship nor have a significant negative effect on professional income. If widely implemented, this shift will create the opportunity for an extensive reduction in the resources allocated to hospitals.

Given the current imperatives to contain the costs of medical care and to reallocate resources to more productive ends, it is in everybody's best interest to reduce the use of marginally effective or unnecessary hospitalizations. In some respects, this is already happening. Over the past two years, we have witnessed an important change in practice patterns in the United States as evidenced by a reduction in the long term trend of increasing hospital utilization. This dimunition is the result of pressures from many sources, but the pivotal factor is that physicians are changing their attitudes about how medicine should be practiced. Our data suggest that the changes that have occurred to date should be viewed as just a beginning. We need to create and sustain an environment where cost effective medical practice is the norm.

For this to happen, practicing physicians must take the lead by examining the pattern of utilization in their own communities and, when necessary, adapting their own practice styles and influencing their colleagues to adapt theirs to the more cost effective practice patterns. A virtue of this approach is the recognition that decisions on cut-backs in service must be highly selective and specific, and that success depends on an informed and cooperative medical staff. It takes into account the nature of uncertainty concerning the value of most medical services and recognizes the need to make clinical choices that reduce demand for hospitalizations that are not worth the costs. It decentralizes the effort to the sites where clinical decisions are made and provides objective information on variations. Most important, the strategy offers a model for cost containment in which the profession can take a leading, not a defensive, role.

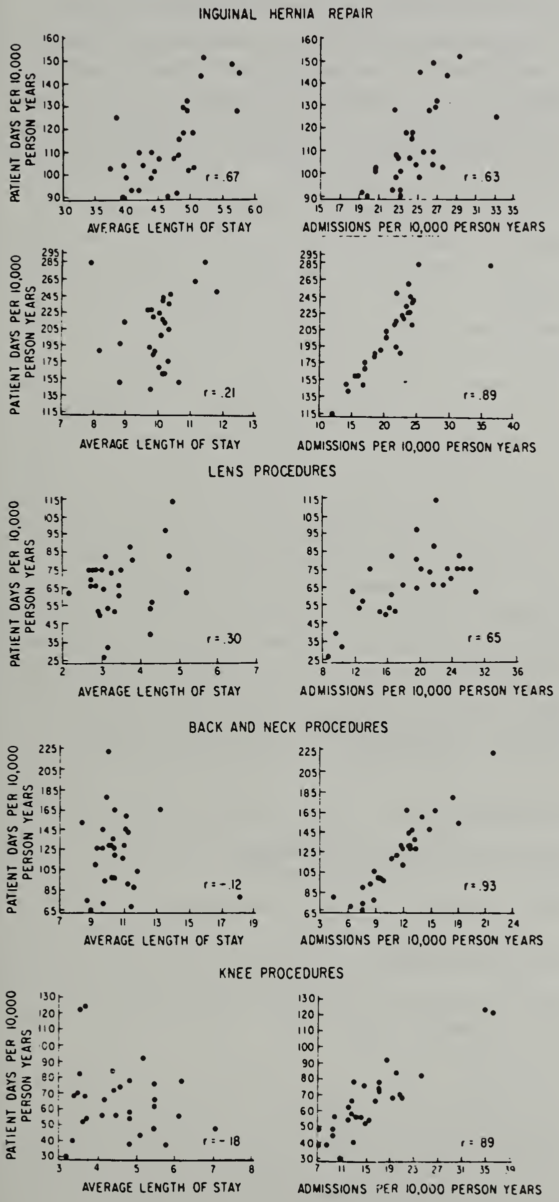


Exhibit 5

Relation between Total Hospital Days and Admission Rate or Average Length of Stay (in Days) for Inguinal-Hernia Repair and Selected Surgical Modified DRGs, in 30 Maine Hospital Markets.

Most of the variation in hospital days among the hospital markets is associated with differences in admission rates rather than in average length of stay, indicating that admission policies are more important than length-of-stay decisions as factors affecting hospital use. The exception is inguinal-hernia repair, a low-variation procedure.

Will practicing physicians participate in such efforts? The evidence I have, based on my experiences in Iowa and New England, is that they will indeed respond. Given information on practice patterns in their local and regional markets, a consensus will emerge that it is safe and in the public interest to reduce hospitalization rates for many of the high variation cases I have listed in exhibit four. Government officials, managers of benefit plans, and representatives of public or private interest groups have exercised important, sometimes decisive influences in persuading the medical profession of the need to respond to the challenge. But lacking as they must a detailed understanding of the nature of medical choices or the particular circumstances of a specific decision, they are in no position to deal with such issues as the necessity for hospitalization for a given patient.

The federal government can make two very specific contributions to promote market reforms based on feedback and review of high variation causes of admission. First, as indicated above, it can assure that the Medicare database is available for the construction of market area specific reports. Second, it can promote population-based utilization review in hospital markets as part of the strategy for implementing the PRO program.

There are important reasons why the federal government should act. With the adoption of the DRG system, new controls on unit costs are now in place. But the level of variation for utilization rates is generally much greater than for unit prices. (Exhibit 5) Since the DRG payments for services in any given hospital market depends upon diagnosis-specific admission rates, per capita reimbursements for most DRGs will typically show a three- and four- and often as much as a tenfold difference among neighboring areas. Many of these DRGs are highly variable because in some communities patients are cared for in the hospital while in others they are treated outside of the hospital.

Some of the variation in the medical DRGs may represent misclassification of patients, so I am reluctant to extrapolate from the variations seen for specific DRGs to predict the savings that might accrue to the Medicare Trust Fund if the PRO program were able to mobilize the physician community to adopt the more conservative practice styles. However, since hospital reimbursements for all causes vary by more than twofold, adoption of the conservative practice styles could easily result in savings that amount to more than 40 percent of the current outlay for hospitals.

Is there danger here of withholding necessary care or decreasing quality? Some expensive procedures are clearly necessary and costs for these will remain high. I am convinced, however, that it is both safe and in the public's best interest to reduce the use of hospitals for most high variation medical and surgical admissions. Many communities with first class medical care systems have low hospitalization rates. We find many examples of low cost markets where most hospitalizations occur within teaching hospitals. I mentioned already the case of the New Haven market area served by Yale teaching hospitals. Others include the local market area of the University of Wisconsin's teaching hospital in Madison where Medicare reimbursements for hospitalizations in 1982 were $876 per enrollee compared to $1515 in Milwaukee and the University of Iowa's area where reimbursements were $734 compared to $1320 in Des Moines.

Dealing with the Effectiveness Problem

The third part of my plan is to design and implement a program to deal with the unanswered questions concerning the outcomes of many common diagnostic and therapeutic interventions. The overriding question is whether a specific intervention undertaken to treat a condition with a known level of morbidity gets a better result than an alternative treatment. High levels of uncertainty cost billions of dollars nationwide and involve potentially thousands of lives. Reducing the level of uncertainty demands a concerted effort on the part of the private sector as well as government, and we have the means to achieve that objective.

The extent of the variation in use of most medical and surgical treatments as well as a critical review of the literature supporting the assertion for efficacy of specific treatments indicates that the number of outcome studies to be done is very large. Priorities will need to be set, new cost-effective health services research methodologies for evaluating outcomes must be invented and adopted, resources to conduct the studies must be made available and the interest of practicing physicians in carrying out the studies and responding to the results must be cultivated.

I think we can count on physician participation in the design and implementation of such studies. By virtue of their inclination as well as their training, physicians want to practice scientifically sound medicine. That is what is expected of physicians and what physicians expect of themselves. When resources are available to support their participation, they respond in a very positive way. I submit as evidence the program of the Maine Medical Association to evaluate practice variations and cite in particular their program to investigate the outcome implications of prostatectomies undertaken for benign prostatic hypertrophy. After becoming aware of the extensive variation in prostatectomy rates among Maine communities, the urologists in Maine, under the leadership of Dr. Robert Timothy, undertook an extensive examination of the indications for the operation. As is typical for many common treatments, they could find no studies that provided a longer term, systematic follow-up of unselected patients. Because of this defect in the literature, the probabilities for specific kinds of outcomes—both the good and bad ones—could not be estimated in a meaningful way. To correct the situation, the physicians have undertaken a prospective evaluation of the response of patients to this treatment in order to document the changes in morbidity and functional status that relate to the operation. The study, which will provide information on events for up to a year after surgery, is making an important contribution to reduce uncertainty and ignorance concerning the expected outcomes following this operation.

What can we do to make such efforts routine?

Let me deal first with the medical schools. While the country has made a massive investment in basic biomedical science, both the Congress and the nation's medical schools have largely ignored the disciplines that deal directly with the problems of improving clinical decision-making and evaluating health care outcomes—clinical epidemiology, bio-statistics, and clinical decision analysis. Research to improve medical decision-making is an important part of the agenda of schools of Public Health and has received scattered interest from enlightened physicians in many parts of the country. Yet, career opportunities are extremely limited in these disciplines and funding for specific outcome studies seems to be the last on everyone's agenda, except perhaps for randomized trials in selected fields such as cancer chemotherapy. The underdevelopment of these quantitative disciplines in the faculties of the medical schools not only affects the quality and volume of research in this area; it also means that the medical students are receiving little training in the very subjects that promise to make them better evaluators of evidence concerning alternative choices of treatment and more sophisticated participants in studies designed to improve the knowledge base of clinical medicine. If we wish to deal systematically with the clinical dilemmas evidenced by the practice variation phenomenon, we must adjust this imbalance.

How could the federal government help? In addition to the mobilization of the Medicare claims data base I mentioned before, the Department of Health and Human Services could help in a very direct way. Let me close this testimony by suggesting some specific objectives.

Foremost, the topic must be given visibility and priority. I suggest that HHS should make the goal of reducing uncertainty about the outcome implications of commonly used medical and surgical interventions a high departmental priority.

Second, a lead agency should be designated with responsibility for organizing a national strategy for implementing a program of outcome evaluation. The recent expansion of its mandate to include technology assessment suggests the National Center for Health Services Research for the role of lead agency, but, at the same time, Congress appropriated funds at a level below that available last year. Further, I want to underscore that the evaluative effort I am calling for applies to existing and commonly used medical practices. While assessment of new technology is obviously important, the lack of understanding of the value of existing practices needs special and ongoing attention.

Third, the national strategy should include the development in the medical schools of the quantitative disciplines essential to this task, including epidemiology, bio-statistics, decision analysis and computer sciences. This will provide medical students the analytic tools they need to practice informed, cost-effective medical care. The government could promote this needed instruction by directly supporting educational programs in these areas and by linking government awards to medical schools to the establishment of training programs in these vital areas.

Fourth, as part of this strategy, HHS should design and implement an intra- and extra-mural research program that seeks specifically to improve the knowledge base for services purchased under the Medicare program. My suggestion is that a fixed percentage of the Medicare and Medicaid patient care dollars be earmarked for this purpose. In 1984, expenditure from the Medicare Trust Fund totaled about $33 billion nearly all spent on hospital care. Industries commonly invest directly in development of better products. If one-half of one percent of this amount were invested to find out what portion of this $33 billion is well spent and what represents unnecessary and even harmful uses of public resources, the long term cost containment strategies of the federal government would not only be more successful, they would truly promote better health.

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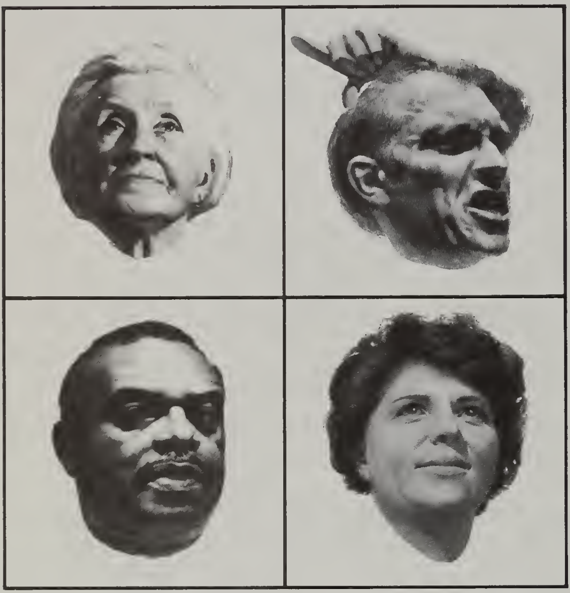

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Reference:
1. Drayer JIM, Weber MA. Current concepts in the evaluation and treatment of patients with mild to moderate hypertension. *Hosp Formul* 1983; 18:164-70.

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Practice Variations in the Provision of Health Care Services

AMERICAN MEDICAL ASSOCIATION

Mr. Chairman and Members of the Committee:

My name is James E. Davis, M.D., and I am a physician in the practice of General Surgery in Durham, North Carolina. I am also the Speaker of the House of Delegates of the American Medical Association. Accompanying me is Harry N. Peterson, Director of the AMA's Division of Legislative Activities. The American Medical Association is pleased to have this opportunity to present its views on the subject of practice variations in the delivery of health care services.

Variations do indeed exist in how treatment is provided for individual patients with similar conditions. In light of the individual nature of medical care coupled with variations in resources and referral patterns, a degree of variation in the provision of health care is normal. Practice variations can arise and provision of care may appropriately vary based on the needs of the individual receiving care, the resources at hand, and the mode of treatment agreed to in the provision of that care. It is also important to realize that the decision to provide a health care service is a decision shared between the patient and physician.

Each patient presents the physician with a unique set of circumstances—medical, social, occupational and others—that the physician must evaluate along with the various treatment choices available. In many cases, this evaluation may be confounded by the lack of absolute certainty about the outcome of medical treatment. In addition, for every given diagnosis there may be more than one treatment that would achieve a desired result that is acceptable within the medical community and to the patient. It is important to recognize that there is still a significant element of "art" in the practice of medicine that comes to bear in every patient evaluation. Like others, the AMA believes efforts directed toward elimination of variations in providing patient care must not result in a reduction in the quality of care by failing to recognize differences between patients and the unique circumstances of providing medical care to each individual patient.

The AMA is concerned about unjustifiable extremes at either end of the health care spectrum. Drastic variations in how patient care is provided can be an indicator of either the provision of inappropriate care or failure to provide appropriate care. Some analysts of this phenomenon may believe that this fact, on its face, automatically signals serious problems in our system of providing health care services. While such is not necessarily the case, the AMA does believe wide variations should be examined closely. We believe that this hearing, Mr. Chairman, can serve a beneficial purpose if judgments founded on proper studies are pursued and if all concerned look at these variations in the delivery of patient care with an eye toward facilitating the delivery of the appropriate level of care to meet the individual needs of patients.

Background

The existence of variations in the delivery of health care services is not a new phenomenon. It has long been recognized that medicine, while based on a broad scientific foundation, still retains significant elements of choice and uncertainty.

The American Medical Association examined the issue of variations in the delivery of health care services in detail during 1978 when it considered the recommendations from the report of the National Commission on the Cost of Medical Care.* In response to Recommendation #14, relating to incentives to provide appropriate care, the AMA adopted the following policy in 1978:

> It is impossible to establish specific hard and fast criteria that could be applied as prima facie evidence of "inappropriateness" of care because of the many patient variables—not only medical, but psychological and social—that enter into every medical decision. It is generally recognized—not only by physicians but by others who have studied this complex issue—that most medical decisions operate along a range of acceptable treatment alternatives, that such alternatives can be established only by physicians, and that considerable disagreement can emerge among physicians of the same specialty and general level of competence treating similar cases.

Presented by James E. Davis, M.D. to the Subcommittee on Labor, Health and Human Services, Education Committee on Appropriations, United States Senate.

*The AMA was instrumental in the development and operation of the National Commission on the Cost of Medical Care which issued its report in 1978 containing 48 recommendations. These recommendations have served as a foundation for AMA activities related to cost-effectiveness. These activities range from strengthening price consciousness and private sector cost containment initiatives to cost containment measures within medical practice.

> This in no way is intended to downgrade the value of any program which enables physicians to compare their practice patterns with those of their peers, nor the use of sample or screening criteria of appropriateness to assist physicians in isolating the practice behaviors which can benefit from such comparisons. (Council on Medical Service Report C, I-78)

This statement still reflects the basic position of the American Medical Association, and the Association has continued its support for efforts to identify variations in the delivery of health care services that could be appropriately modified. While the Association has maintained and is furthering its efforts to aid physicians in addressing inappropriate variations in medical practice, the issue has again been a subject of significant attention due to speculations that limiting practice variables may result in substantial cost savings.

In an article recently published in *Health Affairs* by John E. Wennberg, M.D., Dr. Wennberg indicates that diagnoses with low variation reflect conditions where there is little choice under current recognized medical practice. High variations result when practice options are multiple. His article goes on to state:

> The variation phenomenon appears to be a worldwide phenomenon, not explained by incentives associated with fee-for-service medicine. The pattern of variation for common procedures is similar among fee-for-service hospital markets in Iowa, Maine, Massachusetts, Rhode Island, and Vermont; among health maintenance organizations in the United States; and among the health care regions in Canada, England, and Norway, even though obvious differences exist in the supply of surgeons, the organization and financing of services, and in the cultural and demographic characteristics of hospital market area residents. There is one common factor: physicians in each of these areas of the world read the same medical literature, participate in the same scientific traditions, and share the same scientific uncertainties concerning the value of certain procedures.

Dr. Wennberg goes on to offer a three-part proposal which he believes can have success in "dealing with the health care outcome and cost-containment implications of the medical practice variation phenomenon." Dr. Wennberg's proposal, which recognizes the validity of variation in the practice of medicine, calls for:

- Closer monitoring of medical practice in local hospital markets to be undertaken using epidemiologic techniques to obtain population-based measures of resource allocation, service use, and outcomes of health care. Information obtained from this monitoring should be made available on a continuous basis to interested parties.

- The medical community and qualified researchers to work together to address unanswered questions concerning the effectiveness of many common therapeutic interventions. In this analysis, the overriding question should not be the cost of the intervention, but whether such interventions have beneficial outcomes and are relatively safe.

- The medical community to work to reduce the use of hospitals for marginally indicated conditions, as determined from the monitoring of medical practice.

Comments

The AMA concurs with the approach Dr. Wennberg has proposed. Dr. Wennberg's proposal partially results from his work in a project developed and operated by the Maine Medical Association with funding from the Commonwealth and Robert Woods Johnson Foundations. Dr. Wennberg's work in Iowa has been funded by a coalition involving the Iowa Medical Society and the state hospital association. In placing his proposal in operation, Dr. Wennberg has worked closely with local medical and hospital associations to bring together individual health care practitioners and representatives of institutions in which they practice to facilitate study of utilization and resource allocation profiles. Dr. Wennberg has also worked with the Vermont Medical Society to aid it in identifying variations in patient care that appropriately could be limited.

The American Medical Association applauds the work of Dr. Wennberg, and recognizes three significant strengths of the activity he is encouraging:

1. The Wennberg proposal depends primarily on local and regional initiatives to define the community's and region's utilization issues and to develop local problem-solving approaches to address those issues;
2. The use and reliance on peer influence among physicians to bring about changes in practice patterns is the approach most likely to succeed; and
3. This primary approach is aimed at quality of care. The possibility of achieving economies through reduced utilization is a secondary although highly beneficial result.

The foregoing types of activities promoted by Dr. Wennberg are consistent with the Association's support of physician-sponsored peer review and the initiatives undertaken by many state medical societies to take an active role in Medicare's recently initiated Peer Review Organization program. We believe that the activities are properly focused toward education and voluntary practice modification rather than intrusive governmental intervention. A centralized cookbook approach for standardizing medical practice based upon averages should be avoided.

Current AMA Activities

The American Medical Association recognizes that variations in practice patterns constitute a challenge that needs to be addressed aggressively. The Association supports studies, including the ongoing RAND-UCLA Health Services Utilization Study, that are designed to contribute to a better understanding of health services utilization. The AMA is also undertaking efforts to eliminate inappropriate variations in medical practice. The Association has determined that there are a number of core factors that must individually be examined in analyzing existing variations in providing patient care. These core factors include:

- the presence within a given service area of varying levels of health resources;
- differences in physician practice styles that result from scientific uncertainties concerning the value of certain procedures; and
- individual differences among physicians that are based on such factors as education, specialty training, involvement with teaching, and patient case-mix.

The American Medical Association has underway several projects, discussed below, aimed at providing practicing physicians with information to aid them in making appropriate patient care decisions. We believe that these efforts are consistent with Dr. Wennberg's proposal.

Medical Education

A key element in addressing inappropriate variations in health care practice is to educate future physicians in this country of the value of cost-effectiveness in providing quality health care. The provision of appropriate high quality care in a cost-effective way is facilitated by physicians educated and sensitized to cost considerations.

The AMA adopted Recommendation 38 from the National Commission on the Cost of Medical Care in 1978 calling for:

> Medical, dental and osteopathic schools (to) develop curricula designed to expose students to the economics of the care they deliver, the nature of resource scarcity, and a variety of health care settings.

Since the adoption of this policy, virtually every United States medical school has incorporated economic issues into its curriculum. The 127 medical schools in the country have approached the goal of incorporating cost containment and other economic issues into their curriculum in the following manner:

- Four schools have separate required courses in cost containment;
- Seventy-eight schools include material on cost containment in other required courses;
- Seventeen schools have separate elective courses on cost containment; and
- Thirty-two schools include material on cost containment in other elective courses.

This activity will aid the medical community in becoming increasingly aware of the cost effectiveness of many common therapeutic interventions. It is expected that emphasis on the provision of cost effective care will lead to an early choice of the most economic and effective treatment mode, and that this will tend to limit variations in patient care. Also, this type of educational activity will affect directly one of the core factors of variations in medical practice: physician education.

The Diagnostic and Therapeutic Technology Assessment Project

The AMA inaugurated the Diagnostic and Therapeutic Technology Assessment Project (DATTA) in 1982 in response to concerns over the safety, effectiveness, and indications for use for the rapidly growing arsenal of medical technologies. This project is designed to aid the AMA in responding to concerns about the relative merits of new and existing technologies in medical practice, education, and research. Through the publication of DATTA evaluations, the AMA is working to clarify questions relating to the efficacy of new and existing medical technology and procedures. The project also will assist in determining the issues of obsolescence of existing technology. This activity directly addresses questions of scientific uncertainties that can lead to practice variations. (Background documents that describe the DATTA project and its operation in greater detail and set forth the status of DATTA evaluations are attached as Appendix I.)

Since the initiation of the DATTA program in late 1982, this project has published opinions on 22 subjects; a dozen more subjects are currently under review. The results of all DATTA reviews are published in a special section of the *Journal of the American Medical Association* (*JAMA*). This activity is an important component in alerting physicians and other health care providers to accepted practice modes and changes in practice. This activity is a continuing effort that should guide physician decisions in medical care for many years to come. DATTA should have a significant long-term impact on assuring appropriate patient care throughout the country.

Cost Effectiveness Network

The AMA, in cooperation with the American Hospital Association and the Federation of American Hospitals, has established a network of 85 hospitals throughout the country along with their medical staffs that is taking part in experiments to evaluate a variety of cost effectiveness projects. The first project implemented within this network, a protocol for holding economic grand rounds, has a potential to limit inappropriate practice variations. (An implementation guide for economic grand rounds has been published and is generally available. A copy of this implementation guide is attached to this statement as Appendix II.) The purpose of the economic grand rounds program is to enhance physician awareness of the cost and necessity of services ordered. The four operational goals of this program are:

- To encourage practicing physicians to reflect on their practice patterns in the context of cost effectiveness issues;
- To reinforce clinical behavior which is directed toward the cost effective delivery of high quality medical care;
- To change physician behavior where appropriate to reflect more cost effective delivery of high quality care; and

- To stimulate additional subsequent activities geared to foster the cost effective delivery of medical care.

The second project, a study designed to improve the efficiency of the utilization of respiratory care services, currently being analyzed through the cost effectiveness network should also have a long-term impact on health care variations. When this second study is completed, it too will be made generally available.

Health Care Coalitions

The American Medical Association has recognized the appropriate role of many private sector interests in holding down rising health care costs and in effect to limit inappropriate variations in the delivery of health care services. The AMA started working with state and county medical societies in 1979 in the development of community-based health care coalitions. These coalitions work to bring together physicians, business and labor representatives, hospital management, and insurors to provide local forums to seek ways to contain costs, maintain accessibility, maintain high standards of health care, and to limit inappropriate variations in the delivery of health care services.

Currently, 31 state medical societies and 133 of the major metropolitan county medical societies participate in a coalition. This represents a substantial increase over just two years ago when only 14 state medical societies and 47 of the metropolitan county medical societies participated in such a coalition. The significance of this increase in coalition activity is reflected in the fact that these coalitions have had success in limiting variations in medical practice. This is illustrated by examples of activities in two separate areas of the country, Birmingham, Alabama and Toledo, Ohio, where health care coalitions have successfully identified practice patterns in substantial variance to the rest of the community, and where physician-to-physician communication has resulted in a limitation of this variance.

The AMA believes that such activity by health care coalitions is consistent with the three points of Dr. Wennberg's proposal and that such activity in identifying variations in the provision of patient care services can produce beneficial modifications. The Association will continue encouraging physician participation in health care coalitions and expects that this activity will have continued success in limiting variations in the future.

Future AMA Activities

In October, the AMA Board of Trustees approved a report that sets forth future activities of the AMA that are planned to facilitate local physician efforts to deal with utilization variations. This report will be considered by the AMA's House of Delegates at its December 1984 meeting. This plan calls on the Association to initiate the following activities:

- Disseminate on a broad basis a series of utilization reports that will provide the AMA Federation (national specialty medical societies, state, county, and major metropolitan medical societies) with regional data on hospital lengths of stay and admissions, and that will report on emerging trends in the utilization of medical services;

- Publish and distribute brief case studies on medical society initiatives to involve practicing physicians in the reassessment and alteration of utilization patterns; and

- Publish information that will provide readers with a review and analysis of selected studies conducted by peer review organizations and others that assess state and local utilization variations for specific procedures and diagnoses.

In addition, the Association is currently in the process of compiling information on activities undertaken by state medical societies and other organizations to analyze geographic variations in the delivery of health care services.

Conclusion

In dealing with the issue of variations in the delivery of health care services, it is important to keep in mind that many variations in and of themselves are not necessarily bad. Variations in the delivery of health care services should not be viewed solely as a potential area for cost savings. Individuals and their individual needs should not be treated based on a "statistical average."

The Association has made a substantial commitment to work toward the goal of eliminating inappropriate variations in the delivery of health care services while at the same time striving to preserve the quality of health care services that the American people both deserve and receive. The AMA believes that the methodology to examine variations in the delivery of health care services that are expounded by Dr. Wennberg and that are being undertaken by the AMA and others on a voluntary basis offer the best hope for achieving the tandem goal of economic savings and an assurance of quality health care for the American people.

Travelers' Diarrhea

NATIONAL INSTITUTES OF HEALTH

Introduction

Diarrhea is by far the most frequent health problem of travelers to developing countries. Of the estimated 300 million international travelers who will cross the world's frontiers this year, at least 16 million persons from industrialized countries, including more than 8 million U.S. residents, will travel to developing countries. Approximately one third of these travelers to developing countries will get diarrhea. The economic impact of travelers' diarrhea (TD) is substantial, because fear of sickness is one of the major deterrents to tourism. International tourists worldwide spend over $100 billion annually, and the economies of many nations depend on this travel. For educational, recreational, political, and financial reasons, this international exchange should be fostered.

The incidence of TD varies markedly by destination and may depend in part on the number of dietary indiscretions made by the traveler and on the style of travel. Travelers' diarrhea is caused by a variety of infectious agents, and the spectrum of clinical illness varies considerably. However, this illness in travelers is usually not severe; high fever, vomiting or bloody stools occur only in a minority of cases.

Dietary prudence and hygienic measures are safe and simple preventive techniques, but they do not eliminate entirely the risk of diarrhea. Prophylactic measures such as antidiarrheal drugs and oral antimicrobial agents have been used. Travelers' diarrhea is treated with a variety of regimens, including oral electrolyte solutions, antidiarrheal compounds, and antimicrobial drugs, prescribed either singly or in combination.

There continues to be a debate concerning whether the risk of antimicrobial agents is worth the benefit; whether early treatment of ill travelers is preferable to daily prophylaxis of all travelers; whether all currently employed treatment strategies are useful; and whether given groups of travelers, such as vacationers, students, or business travelers, should be selectively advised to follow special regimens.

To resolve some of these questions, the National Institutes of Health Office of Medical Applications of Research and the National Institute of Allergy and Infectious Diseases convened a Consensus Development Conference on Travelers' Diarrhea from Jan. 28 to 30, 1985. After 1½ days of expert presentation of the available data, a consensus panel of epidemiologists, biostatisticians, microbiologists, pediatricians, internists, infectious diseases specialists, travel experts, and lay representatives considered the evidence and agreed on answers to the following questions.

1. What is the epidemiology of travelers' diarrhea, and why is it important?
2. What causes travelers' diarrhea?
3. What prevention measures are effective for travelers' diarrhea?
4. What treatment measures are effective for travelers' diarrhea?
5. What should be the direction of future research?

1. What Is the Epidemiology of Travelers' Diarrhea, and Why Is It Important?

Travelers' diarrhea is a syndrome characterized by a twofold or greater increase in the frequency of unformed bowel movements. Commonly associated symptoms include abdominal cramps, nausea, bloating, urgency, fever, and malaise. Episodes of TD usually begin abruptly, occur during travel or soon after returning home, and are generally self-limited. Within this context, travelers at risk are defined as individuals from industrialized countries visiting for a period of up to one month a region or country where there is an increased risk of developing diarrhea. The public health and medical importance of TD is related to the large numbers of travelers who place themselves at risk each year. Furthermore, TD is but a mild reflection of the severe underlying problem of diarrhea among children in the tropics.

From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, MD.

Reprint requests to Office of Medical Applications of Research, Bldg. 1, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

The most important determinant of risk is the destination of the traveler. Attack rates in the range of 20% to 50% are commonly reported, but recent data are available from relatively few countries. The best available estimates of country-specific attack rates have been reported for Swiss travelers. Examples of high-risk destinations include most of the developing countries of Latin America, Africa, the Middle East, and Asia. Intermediate-risk destinations include most of the Southern European countries and a few Caribbean islands. Low-risk destinations include Canada, Northern Europe, Australia, New Zealand, the United States, and a number of the Caribbean islands.

Travelers' diarrhea is slightly more common in young adults than in older people. The reasons for this observation are unclear but may include a lack of acquired immunity, more adventurous travel styles, and different eating habits. Attack rates are similar in men and women. The most common onset of TD is usually within the first week, but onset may occur at any time during the visit and even after the return home.

Travelers' diarrhea is acquired through ingestion of fecally contaminated food and/or water. Both cooked and uncooked foods may be implicated if improperly handled. Especially risky foods include raw vegetables, raw meat, and raw seafood. Tap water, ice, unpasteurized milk and dairy products, and unpeeled fruits are associated with increased risk of TD; bottled carbonated beverages (especially flavored beverages), beer, wine, hot coffee or tea, or water boiled or appropriately treated with iodine or chlorine are safe.

The eating place appears to be an important variable, with private homes, restaurants, and street vendors listed in order of increasing risk.

Travelers' diarrhea typically results in four to five loose or watery stools per day. The median duration of diarrhea is three to four days. Ten percent of the cases persist longer than one week, approximately 2% longer than one month, and less than 1% longer than three months. Persistent diarrhea is thus quite uncommon and may differ considerably from acute TD with respect to etiology and risk factors. Travelers may experience more than one attack of TD during a single trip. Approximately 15% experience vomiting, and 2% to 10% may have diarrhea accompanied by fever or bloody stools or both. Rarely is TD life threatening. In an extensive survey of several hundred thousand Swiss travelers, no deaths could be attributed to TD.

2. What Causes Travelers' Diarrhea?

Infectious agents are the primary cause of TD. This statement is based on investigations designed to isolate known infectious organisms from diarrheal stools of tourists and on studies that demonstrated the efficacy of antibacterial agents. In addition, induced disease in volunteers has confirmed the causal role of the putative bacterial and viral agents in producing TD.

All travelers from industrialized countries going to developing countries quickly develop a rapid, dramatic change in their intestinal flora. These new organisms often include the potential enteric pathogens. Those who develop diarrhea have ingested an inoculum of virulent organisms sufficiently large to overcome individual defense mechanisms, resulting in symptoms.

Enteric Bacterial Pathogens

Enterotoxigenic *Escherichia coli* is the most common causative agent of TD in all countries where surveys have been conducted. The discovery and understanding of the mechanisms of action of cholera enterotoxin led to investigations that demonstrated enterotoxins in *E coli* and other bacteria. These organisms adhere in the small intestine, where they multiply and produce and enterotoxin (either heat stable or heat labile) that causes fluid secretion and diarrhea.

Identification of the enterotoxigenic *E coli* is a difficult task, requiring sophisticated techniques that remain somewhat insensitive.

Other types of *E coli* have different virulence traits. These have been termed enteroadherent, enteroinvasive, and enteropathogenic *E coli.* No systematic search for these other types of *E coli* has been conducted in patients with TD. Limited data suggest that they are a minor cause of TD.

Salmonella gastroenteritis is a well-known disease that occurs throughout the world. In the industrialized nations, this large group of organisms is the most common cause of outbreaks of food-associated diarrhea. In the developing countries, the proportion of cases of TD caused by salmonellae varies but is not high. Salmonellae also can cause dysentery characterized by bloody mucus-containing small-volume stools.

Shigellae are well known as the cause of bacillary dysentery. They cause TD in about 5% to 15% of travelers in a few countries. Few of the infected travelers had dysentery, but most had watery diarrhea.

Campylobacter jejuni is a common cause of diarrhea throughout the world. Recent, limited data have shown that *C jejuni* is responsible for a small percentage of the reported cases of TD, some with bloody diarrhea. Additional studies are needed to determine how frequently it causes TD.

Vibrio parahaemolyticus is associated with the ingestion of raw or poorly cooked seafood and has caused TD in Japanese people traveling in Asia. How frequently it causes disease in other areas of the world is unknown.

Other potential bacterial pathogens, including *Aeromonas hydrophila, Yersinia enterocolitica, Plesiomonas shigelloides, Vibrio cholerae* (non-01), and *Vibrio fluvialis,* are known to cause diarrhea in children and adults. In Thailand, *Aeromonas* and *Plesiomonas* have been isolated from stools of Peace Corps volunteers who had TD. A better appreciation of the importance of each of these bacteria as causative agents of TD requires a more intensive search for them, using appropriate selective isolation media or rapid diagnostic techniques.

Viral Enteric Pathogens—Rotavirus and Norwalk-like Virus

Along with the newly acquired bacterial flora, many viruses also are acquired. In six studies, for example, 0% to 36% of diarrheal illnesses (median, 22%) were associated with rotaviruses in the stools. However, a comparable number of asymptomatic travelers also had rotaviruses, and up to 50% of symptomatic rotavirus infections were associated with nonviral pathogens. Ten percent to 15% of travelers develop a serologic conversion to Norwalk-like viruses. The roles of adenoviruses, astroviruses, coronaviruses, enteroviruses, or other viral agents in causing TD are even less clear. Although viruses are commonly acquired by travelers, they do not appear to be frequent causes of TD in adults.

Parasitic Enteric Pathogens

The few studies that have included an examination for parasites reveal that 0% to 9% have *Giardia lamblia* or *Entamoeba histolytica. Cryptosporidium* has recently been recognized in sporadic cases of TD.

Dientamoeba fragilis, Isospora belli, Balantidium coli, or *Strongyloides stercoralis* may cause occasional cases of TD. While not major causes of acute TD, these parasites should be sought in persisting unexplained cases.

Unknown Causes

No data have been presented to support noninfectious causes of TD such as changes in diet, jet lag, altitude, and fatigue. At present, current evidence indicates that in all but a few instances (eg, drug-induced or preexisting gastrointestinal tract disorders) an infectious agent or agents cause diarrhea in tourists.

Even with the application of the best current methods for detecting bacteria, viruses, and parasites, in various studies 20% to 50% remain without recognized etiologies. The unrecognized causes may be attributed to:

- Recognized pathogens that were not uniformly sought in every study (such as *Campylobacter, Aeromonas, Yersinia, Plesiomonas, Vibrios,* viruses, and parasites like *Cryptosporidium).*
- Unrecognized pathogens.
- Known bacterial pathogens that were not detected. Our best methods for detecting enterotoxigenic *E coli* and *Shigella,* for example, are insensitive and miss 30% to 40% of cases in outbreak or volunteer studies.

3. What Prevention Measures Are Effective for Travelers' Diarrhea?

There are four possible approaches to prevention of TD. They include instruction regarding food and beverage preparation, immunization, use of nonantimicrobial medications, and prophylactic antimicrobial drugs.

Data indicate that meticulous attention to food and beverage preparation, as mentioned above, can decrease the likelihood of developing TD. Most travelers, however, encounter great difficulty in observing the requisite dietary restrictions.

No available vaccines and none that are expected to be available in the next five years are effective against TD.

Several nonantimicrobial agents have been advocated for prevention of TD. Available controlled studies indicate that prophylactic use of difenoxin, the active metabolite of diphenoxylate (Lomotil), actually increases the incidence of TD, in addition to producing other undesirable side effects. No antiperistaltic agents (eg, diphenoxylate and loperamide hydrochloride [Imodium]) are effective in the preventing TD. No data support the prophylactic use of activated charcoal.

Bismuth subsalicylate, taken in liquid form as the active ingredient of Pepto-Bismol (2 oz. four times daily), has decreased the incidence of diarrhea by 60% in one study. Available data are not extensive enough to exclude a risk to the traveler from the use of such large doses of bismuth subsalicylate over a period of several weeks. In patients already taking salicylates for arthritis, large concurrent doses of bismuth subsalicylate can produce toxic serum concentrations of salicylate. On the basis of its modest potential benefit achieved with large doses, together with its uncertain risks, bismuth subsalicylate is not recommended for prophylaxis of TD.

Controlled data are available on the prophylactic value of several antimicrobial drugs. Enterovioform and related halogenated hydroxyquinoline derivatives (eg, clioquinol, iodoquinol, Mexaform, Intestopan, and others) are not helpful in preventing TD, may have serious neurological side effects, and should never be used for prophylaxis of TD.

Carefully controlled studies have indicated that two agents—doxycycline and trimethoprim-sulfamethoxazole, when taken prophylactically, are consistently effective in reducing the incidence of TD by 50% to 86% in various areas of the developing world. One study shows that trimethoprim alone is also effective.

The benefits of widespread prophylactic use of doxycycline or trimethoprim-sulfamethoxazole or trimethoprim alone in several million travelers must be weighed against the potential drawbacks. The known risks include allergic and other side effects (such as common rashes, photosensitivity of the skin, blood disorders, Stevens-Johnson syndrome, and staining of the teeth in children) as well as other infections that may be induced by antimicrobial therapy (such as antibiotic-associated colitis, *Candida* vaginitis, and, possibly, *Salmonella* enteritis). Because of the uncertain risk of widespead administration of these antimicrobial agents, their prohylactic use is not recommended. Nor is there any basis for recommending their use prophylactically for special

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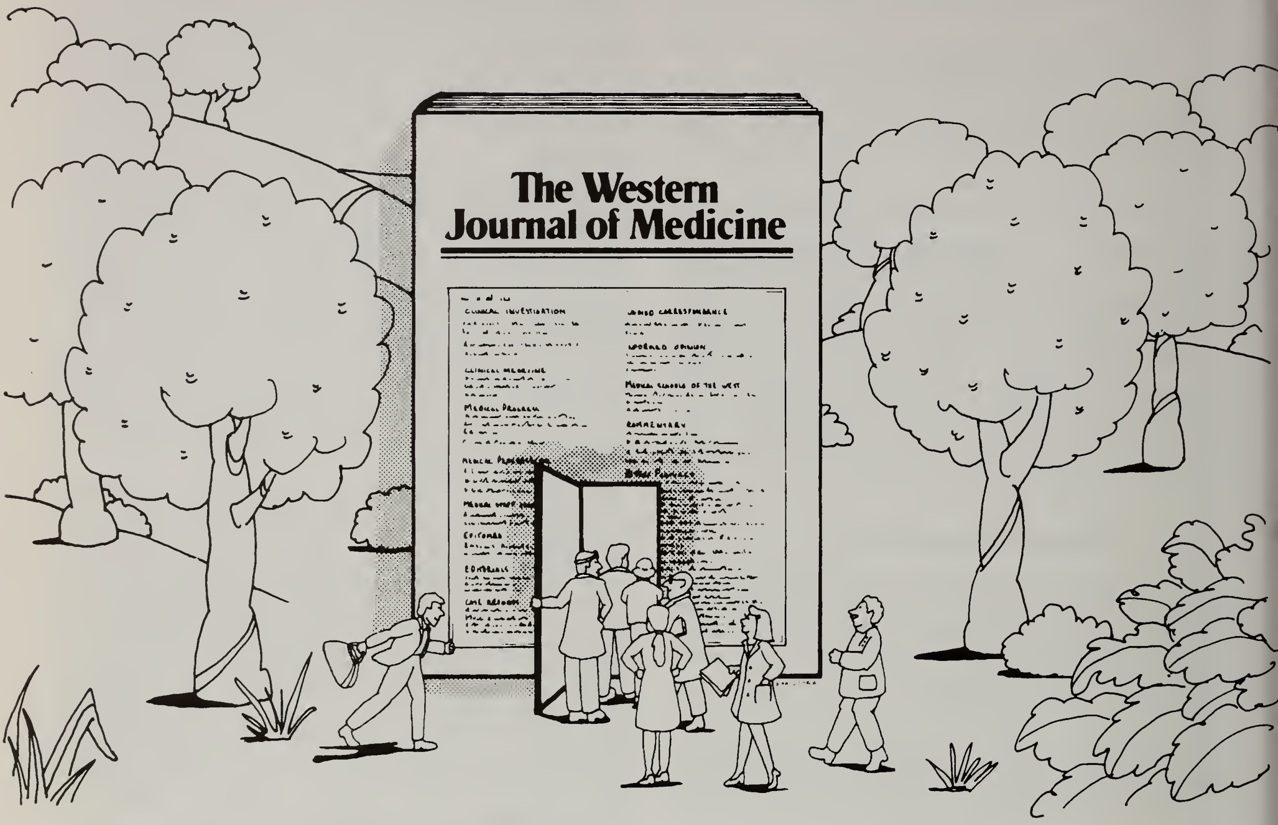
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groups of travelers. For example, the physician should not recommend an agent for prophylactic use by a business traveler and deny such use by a honeymoon couple. Furthermore, there is no documented evidence that there are any groups of disease entities that are worsened sufficiently by an episode of TD to risk the rare undesirable side effects of prophylactic antimicrobial drugs.

The selective pressure of prophylactic use of antimicrobial agents on the genetic pool of antimicrobial resistance is of concern but may be insignificant in light of the widespread use of over-the-counter antimicrobial agents in many developing countries. The increasing frequency of resistance to multiple antimicrobial agents (including both doxycycline and trimethoprim-sulfamethoxazole) will limit the effectiveness of these agents in many areas.

Available data support only the instruction of travelers in regard to sensible dietary practices as a prophylactic measure. On the basis of apparent risk-benefit ratios, prophylactic antimicrobial agents are not recommended for travelers. This recommendation is justified by the excellent results of early treatment of TD as outlined below. By avoiding prophylactic antimicrobial agents, only those people traveling to high-risk areas who develop moderate to severe TD (less than 30% of travelers at risk) will be exposed to the side effects of antimicrobial agents, and the exposure will be restricted to three days or less in those individuals. Some travelers may wish to consult with their physician and may elect to use prophylactic antimicrobial agents for travel under special circumstances, once the risk and benefits are clearly understood.

4. What Treatment Measures Are Effective for Travelers' Diarrhea?

Individuals with TD have two major complaints for which they desire relief—abdominal cramps and diarrhea. Many agents have been proposed to control these symptoms, but few have been demonstrated to be effective by rigorous clinical trials.

Nonspecific Agents

A variety of "adsorbents" have been used in the treatment of diarrhea. For example, activated charcoal has been found ineffective in the treatment of diarrhea. Kaolin and pectin have been widely used for diarrhea. The combination appears to give the stools more consistency but has not been shown to decrease cramps and frequency of stools or to shorten the course of infectious diarrhea.

Lactobacillus preparations and yogurt have also been advocated, but no evidence supports these treatments for TD.

Bismuth subsalicylate preparation (1 oz. every 30 minutes for eight doses) decreased the rate of stooling by half in a study of travelers with diarrhea when compared with a placebo group. However, there was no difference between the two groups in stool output in the first four hours of the study. There is concern about taking, without supervision, large amounts of bismuth and salicylate, especially in individuals who may be intolerant to salicylates, who have renal insufficiency, or who take salicylates for other reasons.

Antimotility Agents

Antimotility agents are widely used in the treatment of diarrhea of all types. Natural opiates (paregoric, deodorized tincture of opium, and codeine) have long been used to control diarrhea and cramps. Synthetic agents, diphenoxylate and loperamide, come in convenient dosage forms and provide prompt symptomatic but temporary relief. However, they should not be used in patients with high fever or with blood in the stool. The use of these drugs should be discontinued if symptoms persist beyond 48 hours. Diphenoxylate and loperamide should not be used in children younger than 2 years.

Oral Fluids

Most individuals with TD do not develop serious dehydration. Fluid and electrolyte balance can be maintained by potable fruit juices, caffeine-free soft drinks, and salted crackers. The individual with TD should avoid alcohol and caffeine-containing beverages. Dairy products aggravate diarrhea in some people and should be avoided. Individuals with severe dehydration may require special fluid and electrolyte replacement in the form of oral replacement solutions such as those recommended by the World Health Organization.

Antimicrobial Treatment

Travelers who develop diarrhea with three or more loose stools in an eight-hour period, especially if associated with nausea, vomiting, abdominal cramps, fever, or blood in the stools, may benefit from antimicrobial treatment. A typical three- to five-day illness can be shortened to one to 1½ days by effective antimicrobial agents. Those best studied to date are trimethoprimsulfamethoxazole, 160 mg of trimethoprim and 800 mg of sulfamethoxazole, or trimethoprim alone, 200 mg taken twice daily. Preliminary evidence suggests that doxycycline taken 100 mg twice daily is also effective. Three days of treatment is recommended, although two days or fewer may be sufficient. Nausea and vomiting without diarrhea should not be treated with antimicrobial drugs.

Precautions in Children and Pregnant Women

Although children do not make up a large proportion of travelers to high-risk areas, some children do accompany their families. Teenagers should follow the advice given to adults, with possible adjustment of doses of medication. Physicians should be aware of the risks of tetracyclines to children younger than 12 years. There is a paucity of data available about usage of antidiarrheal drugs in children. Drugs should be prescribed with caution for pregnant women and nursing mothers.

Summary Recommendation for Treatment

Travelers' diarrhea is usually a mild, self-limited disorder, with complete recovery even in the absence of therapy; hence, therapy should be considered optional.

1. Fluids should be taken as described above.
2. If rapid relief of symptoms is desired after one or two unformed stools accompanied by cramps, nausea, or malaise, diphenoxylate or loperamide may be taken. An alternative is to start treatment with bismuth subsalicylate (1 oz. every 30 minutes for eight doses). Although this regimen decreases the number of stools and increases their consistency, the beneficial activity of bismuth subsalicylate is somewhat slower than that of antimotility drugs.
3. If it is important to shorten the course or decrease the severity of moderate to severe TD, antimicrobial agents may be taken. After three or more loose stools with symptoms, consideration can be given to a short course of trimethoprim-sulfamethoxazole or trimethoprim alone or doxycycline.
4. A small percentage of travelers have persisting diarrhea with serious fluid loss, fever, and blood or mucus in the stools. This suggests that a more serious illness is involved, and such individuals should seek medical attention.

In conclusion, travelers to areas of high risk should obtain an antimotility drug or bismuth subsalicylate for milder forms of TD, and an antimicrobial agent (trimethoprim-sulfamethoxazole or trimethoprim alone or doxycycline) for more severe TD. Advice concerning side effects of these drugs and various aspects of hygiene and dietary precautions should be obtained. By obtaining the proper drugs in advance, the beleaguered traveler might avoid buying over-the-counter drugs abroad with potentially dangerous ingredients.

5. What Should Be the Direction of Future Research?

Although much has been learned about TD over the past 25 years, there is considerable need for additional research on this important syndrome.

Epidemiology

1. Epidemiologic data are needed from well-designed surveys and prospective studies, especially among travelers to countries and regions not previously examined. These investigations should be expanded to include young and elderly travelers, for whom few data exist.
2. Case-controlled studies should be designed to identify independent risk factors and specific etiologic agents. Such studies should apply all available microbiologic techniques to determine systematically the risk of TD attributable to specific microorganisms in various countries.

Etiology

1. The development of rapid diagnostic techniques (eg, hybridization techniques and monoclonal antibodies) would facilitate all clinical and epidemiologic research.
2. Additional information should be sought regarding the pathogenesis of TD, which should lead to more specific therapeutic interventions.
3. There is a need for careful monitoring of increasing resistance to antimicrobial drugs, especially among the enterotoxigenic *E coli,* in different intermediate and high-risk destinations.
4. There is a particular need to assess the frequency, the risk factors, and microbiology of persistent diarrhea following travel. Better approaches to diagnosis in these patients are needed.

Prevention and Treatment

1. Newer approaches to vaccine and development should be applied to the causal microorganisms of TD.
2. Randomized prospective studies or carefully controlled observational studies should be conducted to determine the true efficacy of dietary restrictions.
3. All agents effective in prevention and treatment of TD should be investigated in larger populations traveling to as-yet-unstudied destinations. Such populations should include children and elderly travelers.
4. Large-scale drug surveillance studies are required to identify important but uncommon toxicities or side effects of various drugs.
5. Minimal effective doses and duration for preventing and treating TD remain to be determined for general therapeutic agents.
6. The active agents and mode of action of bismuth subsalicylate remain to be elucidated, and the tablet form of the drug requires further evaluation.
7. A better understanding of the neurohumoral control of intestinal secretion and its potential interaction with microbial enterotoxins may help in the design of more rational therapeutic strategies for TD. Further study of antisecretory and absorption-enhancing agents may improve pharmacologic therapy and enhance the efficacy and acceptability of oral replacement solutions. Improved understanding of the components of motility that will enhance but not impede absorption may help in the design of rational antimotility therapy.

Summary and Conclusions

Diarrhea is the major health problem in travelers to developing countries. Travel to high-risk areas in Latin America, Africa, the Middle East, and Asia is associated with diarrhea rates of 20% to 50%. The syndrome is caused by an infection acquired by ingesting fecally contaminated food or beverages. *Escherichia coli,* a common species of enteric bacteria, is the leading pathogen, although a host of other bacteria, viruses, and protozoa have been implicated in some cases. Prudent dietary and hygienic practices should be followed, and they will prevent some, but not all, diarrhea. Antimicrobial agents are not recommended for prevention of TD. Such widespread usage in millions of travelers would cause many side effects, including some severe ones, while preventing a disease that has had no reported mortality. Instead of universal antimicrobial prophylaxis, a more sensible approach is rapid institution of effective treatment that can shorten the disease to 30 hours or less in most people. For mild diarrhea, an antimotility drug such as diphenoxylate or loperamide could be taken. Alternatively, bismuth subsalicylate, which works somewhat slower, can be used. For more severe diarrhea, an antimicrobial drug may be used for treatment, and trimethoprim-sulfamethoxazole, trimethoprim alone, and doxycycline are among the choices. These drugs could be carried by the traveler for use in the event of illness. Oral rehydration should be instituted when necessary.

The millions of Americans who travel annually to developing countries and their physicians must be warned of the potential risks of prophylactic antimicrobial drugs, with the attendant side effects in otherwise healthy individuals, and should be informed of the alternative method of prompt, effective treatment of diarrhea.

Members of the Consensus Development Panel were Sherwood L. Gorbach, M.D. (chairman), Boston; Charles C.J. Carpenter, M.D., Cleveland; Robert Grayson, M.D., Miami; Joyce D. Gryboski, M.D., New Haven, Conn; Richard L. Guerrant, M.D., Charlottesville, VA; Thomas R. Hendrix, M.D., Baltimore; Richard B. Hornick, M.D., Rochester, NY; John S. Marr, M.D., M.P.H, New York; Jerry Morris, Boston; B. Frank Polk, M.D., Baltimore; Somerset R. Waters, New York; George W. Williams, Ph.D., Cleveland; Martin S. Wolfe, M.D., Washington, DC.

Members of the Planning Committee were Robert Edelman, M.D. (chairman), Bethesda, MD; Herbert L. DuPont, M.D., Houston; Jerry M. Elliott, Bethesda, MD; Sherwood L. Gorbach, M.D., Boston; Richard Horton, M.D., M.P.H., Bethesda, MD; Myron M., Levine, M.D., M.P.H., Baltimore; John Nutter, Ph.D., Bethesda, MD; Myron G. Schultz, D.V.M., M.D., Atlanta; Michael J. Bernstein, Bethesda, MD; Judy Murphy, Bethesda, MD.

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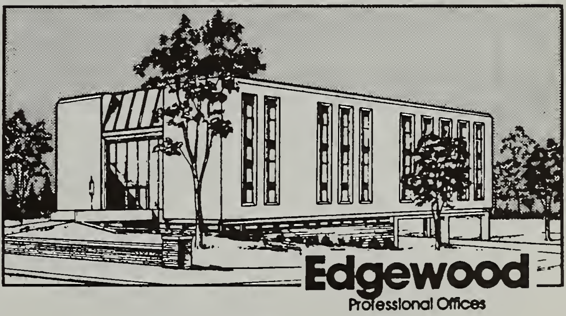

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Month in Washington

Heart Transplants Under Consideration for Medicare

Heart transplantation is being rapidly transformed from an experimental to a therapeutic procedure, federal officials announced at a Washington recent press conference.

They stopped short of guaranteeing Medicare coverage for the procedure, however, saying it needed further study over the next several months.

The government's new review of heart transplantation was prompted by the optimistic results of a long-awaited study by the Battelle Research Center.

The $1.6 million study analyzed the cost and outcome of 441 heart transplant cases performed between 1975 and 1983 at six national transplant centers.

If the government decides to reimburse under Medicare, probably only 85 to 100 of the 42.7 million Americans with cardiovascular disease will be eligible for surgery each year. It is likely that selection criteria will be very stringent, limiting transplants to patients under age 55 and free of other medical problems. Because Medicare is restricted to persons over age 65 or disabled more than two years, few of these beneficiaries will qualify.

Thus, the pricetag may be relatively small. Battelle researchers estimated that the total cost of covering heart transplantation would range from $2 million to $3.5 million a year, much less than the $2 billion a year spent on the controversial End Stage Renal Disease Program (ESRD). Each heart transplant recipient would cost roughly $37,000, compared to the $30,000 spent on each of the 70,000 ESRD dialysis patients each year, but with only a few hundred patients qualifying, the total cost should be low.

The Battelle study found that roughly 80% recipients of heart transplants are alive after 1 year and 50% are alive after 5 years. One-quarter will survive longer than 10 years. An estimated 32% of transplant recipients have gone back to work and 67% consider themselves in "good health." The dramatic increase in survival rates for heart transplant recipients can be traced back to the introduction of cyclosporine in 1980.

Complications, when they appear, are generally linked to immunosuppressive therapy. Five complications are most common: osteoporosis (18.2%), diabetes (14.9%), vision disorders (14.3%), back or spine disorders (8.8%), and cancer (6.1%).

Selection criteria for patients were strict, thus excluding aged or sick patients who would have lowered survival statistics, the study found. The typical recipient was only 42 years old. The six centers accept only persons who are free of active infection, multiple organ dysfunction, illness or rehabilitative difficulties, pulmonary problems, or diabetes.

Funding is a major source of concern for heart transplant recipients. Although the majority of private insurers and 12 states pay for transplant procedures, roughly 70% of recipients paid for pre-transplant and post-transplant expenses out of their own pockets.

In many cases, recipients depended upon the transplant center or direct donations to help fund their procedure.

"It is still a technique to be applied only when a specific set of clinical criteria have been fulfilled," warned HHS Secretary Margaret Heckler. "Data suggest that the rate of success may be accomplished only in medical centers where a "critical mass" of clinical experience and expertise has been gathered."

"We would never take a position that would simply guarantee heart transplants to every American at government expense," she added. "We would oppose universal eligibility for government funding for heart transplants."

* * * *

Supreme Court Agrees to Rule on Abortion . . . Again

The abortion issue will take on new prominence next fall as the Supreme Court justices review two controversial state abortion laws.

The two state laws—in Pennsylvania and Illinois—already have been declared unconstitutional by federal appeals courts. The laws would have given the state governments a major role in the abortion decisionmaking process by specifying how a doctor must perform some abortions and what he must tell his patients.

Prepared by the Washington, D.C. Office of the American Medical Association.

Court approval of the laws could give abortion opponents a green light to pass more restrictive state laws.

On the other hand, rejection of the laws would further protect a woman's right to abortion and reduce the risk of later tampering by a Reagan-appointed member of the court.

The court's decision to review the laws puzzles both advocates and opponents of abortion. It is uncertain, they say, whether the court will try to expand or contract the power of states to regulate abortion.

The two cases to be argued in the next session are:

- an Illinois law that would have made it a crime for a doctor to cause the death of a viable fetus by peforming an abortion. It also would have required that doctors inform their patients that some contraceptives—such as IUDs and morning-after pills—are "abortifacients" that cause fetal death by preventing the fertilized egg to reach the womb.
- a Pennsylvania law would have required that a doctor give a detailed description of the risks of abortion. In addition, it would have imposed a 24-hour waiting period and required that all second trimester abortions be performed in a hospital.

Similar state provisions were overturned two years ago in the Supreme Court's 6-to-3 decision in *City of Akron V. Akron Center for Reproductive Health.* This decision, which rejected the state's role in determining where, and how, an abortion is performed, was assumed to have firmly established a woman's right to the procedure.

* * * *

NIH Says 'No' to Central Transplant Registry

A centralized national registry for bone marrow transplant donors should not be established at this time, a panel of National Institute of Health (NIH) transplant specialists has recommended.

Instead, the medical community should promote and expand the local registries that already exist, it said.

Only one-third of patients needing bone marrow transplants have an HLA-identical sibling donor. Since there is low probability of finding HLA matches in unrelated persons, registries seek large numbers of volunteers to serve as potential donors.

However, of the 70 patients transplanted with marrow from matched unrelated donors, only 20% have survived 3 months; one patient survived 3½ years.

Merging local donor programs into a single national data base could in fact, be counterproductive, the panel said. Donation of bone marrow is highly dependent upon a spirit of voluntarism and altruism; local centers are effective because of the extend of local community involvement. A broad national program could be less effective, it believed.

* * * *

Congressional Budget Bleak for Physicians

Legislators, just returning from a Memorial Day recess, were expected during the first week of June to enter a new round in their annual wrestling match with a federal budget measure.

The action now moves to a conference between the House and the Senate where the Senate is considered likely to back away from its proposal to freeze cost of living adjustments for Social Security and other retirement plans and the House is expected to compromise somewhat on its plan to freeze defense spending.

Debate will also involve the Medicare program where the House has rejected the Senate approach of increasing some beneficiary cost-sharing and of exempting some Medicare "participating" physicians from a plan to continue the current freeze on Medicare fees. Medicaid, too, is an issue since the Senate assumed savings of $1.2 billion over three years while the House would permit inflation adjustments for this program.

The cliff-hanging Senate vote came in the wee hours of the morning on May 12 as California Republican Pete Wilson, recuperating from an appendectomy, arrived by ambulance to tie the vote. Vice President George Bush cast the deciding vote.

The Senate package would cut Medicaid by $1.2 billion in the next three years through "administrative actions." Medicare would be cut by $16.3 billion over the next three years and the current freeze on Medicare fees would continue for "nonparticipating" physicians. Some sort of a fee increase is assumed for physicians "participating" but details have not been worked out.

Hospital diagnosis related group (DRG) rates would be frozen. The adjustment for indirect costs of graduate medical education would be cut in half and the payment for direct graduate medical education costs capped. The measure also would increase the premiums beneficiaries pay for medical services (Part B) under Medicare from the current 25% of costs to 30% of costs.

The House plan, adopted May 22, had a surprisingly smooth passage and no substantive debate on health issues. Much vaguer in its assumptions than the Senate measure, it calls for $13 billion in Medicare savings over the next three years. Some $3 billion is to come from unspecified reforms that are not to include beneficiary cost increases; another $10 billion is to come from a "one-year freeze" on Medicare providers.

While the proposal does not spell out any details, the size of the savings, the lack of any language to the contrary, and reports from House budget staff lead to the conclusion that the freeze on providers includes a continued freeze on all physician fees. There are some indications, however, that many House members would be willing to accept the Senate provision increasing fees for physicians who signed Medicare participating agreements.

Congressional members have reported, however, that although the American Medical Association and other medical groups have strongly protested budget proposals to continue the current Medicare freeze, individual physicians have not expressed significant opposition to this proposal. Their comments have sparked a massive AMA campaign to encourage physicians to communicate their concerns about the budget—particularly the continuation of the physician fee freeze and the cuts in Medicare support of graduate medical education—to their legislators.

Once a compromise has been hewn out by conferees and approved by both the House and Senate, action will move to the Congressional authorizing committees which are directed to meet the budget resolution's specific spending targets for programs under their jurisdiction but can choose their own method of meeting them.

This so-called reconciliation process is likely to begin in mid-June and for Medicare and Medicaid programs will involve the Senate Finance and House Ways and Means Commerce Committees. An adjustment in the physician fee freeze and increases for at least part of the Medicare participating physicians are considered to have a chance of approval during this process.

Other provisions that could be included in a reconciliation package include bringing state and county workers into Medicare, freezing payments only for certain procedures, and experimental physician prospective payment system, capitation payments, and increases in cigarette taxes.

* * * *

GAO Finds Hospital Overpayments

Hospitals have been overpaid under Medicare's prospective pricing system and unless the data the rates are based on are corrected, overpayments could total over $8 billion during the next five years, the General Accounting Office (GAO) has concluded.

In testimony to the House Ways and Means health subcommittee May 14, GAO Associate Director Michael Zimmerman charged that as a result of errors made during the construction of the diagnosis related groups (DRGs), Medicare payments to hospitals will be 4.3% or $940 million higher in fiscal 1986 than they should have been.

The GAO report comes as Congress is considering a freezing DRGs next year and it could serve as a rationale for such a freeze. The Prospective Payment Assessment Commission (PROPAC), which Congress created to give advice on DRG rates, has recommended a formula under which rates would increase 1-3% next year.

If rates are allowed to rise according to the current legislated schedule, the result would be an increase of about 5.1% next year.

But Health Care Financing Administration (HCFA) officials plan to propose regulations June 3 that would freeze the rates. Like the GAO, HCFA contends that the rates were set too high initially.

Hospitals are citing the PROPAC recommendation as evidence that a freeze is untenable, and American Hospital Association officials have told Congress that unless other changes are made in the DRG system, hospitals need at least a 4% increase in fiscal 1986 are to continue services at their current level.

Yet, the AHA and other hospital groups seem resigned to the freeze. At this point they are only pushing for changes. Chief among these are: an increase for hospitals serving a "disproportionate share" of indigent and/or Medicare patients; changes in the wage indexes believed to discriminate against rural hospitals; and some sort of protection for hospitals whose rates would be "rolled back" and not just frozen under President Reagan's budget proposal.

The "disproportionate share" issue has drawn the most attention. Congress had suggested when it created DRGs that an adjustment might be needed for the "disproportionate share" hospitals and had directed the Health Care Financing Administration to define and list such hospitals. HCFA has refused to design an adjustment or to turn over to congress its studies and data on the issue, but the agency now expects a new study by the end of June.

Meanwhile, an angry Ways and Means health subcommittee is working with the American Hospital Association to design its own list. By one estimate, an adjustment might shift about $250 million to these hospitals from all other hospitals.

HCFA has only recently modified a wage price index to take into account parttime employees widely used in rural hospitals, based on a survey of 5,734 hospitals. Overall, hospitals in 27 states (generally in the west and midwest) and the District of Columbia would gain in Medicare payments. Twenty-three states (mostly East of the Mississippi) would suffer overall losses. But the effect would vary by hospital within a state. Slightly more rural areas (27) would profit than would lose (21 and slightly more urban areas (166) would lose than would gain (149).

Congressmen from states that would profit under the new wage index urge that it be applied to new DRG rates to take effect next October. There is general aggreement that there should be no retroactive adjustment.

Although most hospitals agree that both the disproportionate share adjustment and the wage index correction should occur before a freeze, the industry is divided on a proposal to halt the transition to a national DRG rate. As the transition continues, teaching institutions, public hospitals, and facilities in high cost states such as California, Illinois, Massachusetts, Missouri, Wisconsin, and Ohio will be paid less while other facilities in states such as Alabama, Arkansas, Georgia, New Jersey, Pennsylvania, Tennessee, and North Carolina will see substantial gains.

Normally, the annual update in DRG rates would have alleviated the impact of the transition. But if rates are frozen, some hospitals will receive considerably lower payments per case in fiscal 1986 than in 1985.

A coalition that includes the Association of American Medical Colleges, the National Association of Public Hospitals and several state associations wants to stop the transition and Rep. Robert Matsui (D-CA) has introduced legislation to this end. The AHA supports the delay and the Federation of American Hospitals board is split on the issue. Another group of nine state associations is opposing any delay.

* * * *

Attitudes on HMOs Changing

Although most American physicians still think traditional fee-for-service medicine offers higher quality care than HMOs, 50% of all physicians now have a favorable attitude toward HMOs. Furthermore, HMO patients express greater satisfaction with the quality of their physicians than do non-HMO members.

These results from a just-published survey by Louis Harris Associates contrast with earlier surveys which found in 1980-81 that only 36% of physicians were favorably disposed toward HMOs and that non-HMO patients were more satisfied with the quality of their physicians than were HMO members. Conducted last fall for the Henry J. Kaiser Family Foundation, the survey results are cited as "dramatic evidence that physicians have changed their outlook on HMOs."

The survey found that about 9% of privately-insured American families now have an HMO member and that 40% of those interviewed were interested in joining an HMO. Among the elderly who have been targeted for an HMO enrollment effort, only 6% exhibited a strong interest while another 12% showed some interest. HMOs are growing most rapidly on the East Coast and in the under 40 population.

* * * *

Fraud Bill Moves Through House

A bill that would strengthen the government's authority to exclude disciplined physicians from Medicare and Medicaid is moving steadily through the House of Representatives but has not progressed in the Senate.

The bill, HR-1868, was approved unanimously by both the House Ways and Means and Energy and Commerce committees, thus clearing the way for consideration by the full House. The law is aimed at loopholes in the current law which permit a physician who loses a license in one state to treat Medicare and Medicaid patients in another state in which he also holds a license. Current law also does not permit the exclusion from a federal program of a provider who has been barred from another federal program.

HR-1868 would authorize the Department of Health and Human Services to bar from any federal program any provider who: was convicted of abusing program finances, patients, or controlled substances; lost or surrendered his license for cause in any state; provided excessive or poor quality care. If the provider was convicted of a criminal act against Medicare or one of its patients, the minimum period of the exclusion would be five years.

The American Medical Association has supported the aim of the bill but did not support the minimum five-year exclusion and contended that the authority to exclude physicians who provided excessive or poor quality care already exists in the Peer Review Organization law.

Two other bills also were incorporated into HR-1868. One measure that had been opposed by the AMA would allow the Attorney General to revoke the drug prescribing authority of any physician banned from Medicare and Medicaid. The other, which had the general support of the AMA, would authorize civil and monetary penalties against anyone who misrepresents himself as a physician.

Senate Aging Committee chairman John Heinz (R-PA) has introduced similar legislation in the Senate but the bill has not yet to be considered in Committee. Meanwhile, the Reagan administration reportedly is developing its own fraud and abuse measure and expects to have it introduced in the Senate.

* * * *

AMA Loses Super-Pro Bid

A contract to monitor the work of Medicare's Peer Review Organizations (PROs) will not go to the American Medical Association, which had submitted two bids for the so-called Super-PRO.

Although the contract has not yet been awarded, the AMA was notified that it is no longer in the running for the contract. The letter of notification concluded that the AMA proposal is "not within the competitive range, price and other factors considered."

The notification comes amid rumors that budget cuts within the Health Care Financing Administration have left the agency with less than $2 million for the Super-PRO. It follows an earlier funding problem which forced PRO officials to scale down and reissue their Super-PRO bid request after the AMA and the other three bidders all came in at prices above the $5 million the agency was then reported to have set aside for the winning bidder.

The AMA reportedly was one of 13 bidders in a field that has now been narrowed to two. A selection is expected by about June 10.

The AMA reportedly was one of 13 leaders in a field that has now been narrowed to two. A selection is expected by about June 10.

The AMA had no immediate comment on the loss of the Super-PRO contract. At a Senate hearing earlier this spring, however, William Felts, M.D., a member of the Association's council on legislation, said that while the contract should go to the AMA, the association would continue to oversee the PROs through its own special monitoring program even if the contract went to another bidder.

(Continued on page 477)

Recent Trends in Medical Professional Liability

AMA CENTER FOR HEALTH POLICY RESEARCH

Medical professional liability is continuing to be a major problem facing physicians. Recent trends indicate that claims and annual premiums for liability insurance are on the increase. There is growing evidence that these trends have lead physicians to attempt to reduce the risk resulting from claims through the practice of defensive medicine. In this report, the degree to which the risk to physicians has increased and the extent that physicians have increased the level of defensive medicine they practice are examined. Trends in liability insurance premiums and litigation costs resulting from a claim are also reported.

Trends in the Annual Rate of Claims

An analysis of the average annual rate of claims before and after 1980 indicates that physicians have become more at risk of incurring a claim in the last five years. Table 1 indicates that physicians experienced claims at an average annual rate of 3.0 per 100 physicians prior to 1980 compared to 8.6 claims during the period 1980-84. Although similar information from SMS has been reported on claims for the periods 1979-83 and prior to 1979, survey sampling errors make it inappropriate to compare that information with current results to ascertain short-term trends.

Among specialty groups, surgeons were at the greatest risk of having a claim filed against them during both the 1980-84 time period and the period prior to 1980. These physicians incurred claims at an average annual rate of 4.4 claims per 100 physicians prior to 1980 and 13.9 during the last five years. General and family practitioners experienced claims at an average annual rate of 2.9 claims per 100 physicians prior to 1980 compared to 7.4 during the period 1980-1984. The risk to medical specialists increased the least—their average annual rate of claims was 2.4 per 100 physicians prior to 1980 and 5.7 during the following five years.

The risk to physicians has increased in all four census regions. Physicians in the Northeast were at the greatest risk of incurring a claim in the last five years while physicians in the South were at the least risk. These variations might best be explained by examining claims rates for the individual states that compose each region. This is because the laws which regulate professional liability and influence the rate of claims are enacted at the state level. However, sample size limitations prevent reliable disaggregation of the data used in this report to the state level.

Table 1
AVERAGE INCIDENCE OF MALPRACTICE CLAIMS
BY SELECTED CHARACTERISTICS

	Annual Claims per 100 Physicians	
	1980-1984	*Prior to 1980*
ALL PHYSICIANS	8.6	3.0
Specialty		
General/Family Practice	7.4	2.9
Medical Specialties	5.7	2.4
Surgical Specialties	13.9	4.4
Region		
Northeast	10.7	3.1
North Central	8.2	2.6
South	7.3	2.6
West	8.9	3.7

Increases in Defensive Medicine

Increases in claims have lead physicians to protect themselves through the practice of defensive medicine. There are two types of defensive medicine. "Positive defensive medicine" occurs when a physician performs additional tests or procedures in order to avoid being accused of negligence (for not having performed them) and not because they are perceived as essential. This type of defensive medicine directly increases health care costs. The second type, termed "negative defensive medicine,"

SMS Report, March 1985, Vol. 4, No. 2. Reprinted with the permission of The AMA Center for Health Policy Research.

The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

occurs when a physician avoids certain procedures because legal risks might arise from resulting complications.

Information was collected in the 4th quarter 1984 SMS survey to examine several aspects of "positive defensive medicine." Physicians were asked if they *increased* the amount of defensive medicine they practiced in the last 12 months. In other words, the information reflects additions to the level of defensive medicine that may already have been performed.

Overall, 42% of physicians took at least one measure indicating an increase in the practice of defensive medicine in the last 12 months. For individual defensive measures, the results (see Table 2) indicate that:

31% of physicians maintained more detailed records.
20% prescribed more diagnostic tests and/or treatment procedures.
17% increased follow-up visits.
17% spent more time with patients.

All these responses to increased professional liability risks directly contribute to higher health care costs.

The decision to practice defensive medicine is based on physicians' perceptions of their risk of incurring a claim. As shown in Table 2, physicians with at least one claim in their career were more likely to increase the level of defensive medicine they practiced than physicians who never incurred a claim. This suggests that perception of risk is influenced by a physician's own claims experience as well as other factors such as their liability insurance premium rates and colleagues' claims experiences.

Among specialty groups, it is expected that those specialties which have incurred more claims in the past would practice more defensive medicine. This hypothesis is supported by the results. More surgeons and general and family practitioners tended to increase their defensive medicine practices in the last 12 months than medical specialists. However, general and family practitioners were more likely than surgeons to have increased several defensive medicine practices despite the fact that surgeons had incurred claims at a higher rate. It is possible that surgeons had already been practicing defensive medicine to a greater extent and did not feel the need to increase their current level.

Table 2
PERCENT OF PHYSICIANS THAT INCREASED THE LEVEL OF DEFENSIVE MEDICINE THEY PRACTICED DURING 1984

	Percent			
	Maintaining More Detailed Records	*Increasing Tests or Treatment Procedures*	*Increasing Follow-up Visits*	*Increasing Time Spent with Patients*
ALL PHYSICIANS	31.0%	20.0%	17.0%	17.0%
Physicians with no claims	24.7	16.1	13.7	13.9
Physicians with at least one claim	41.1	26.6	22.2	22.4
Specialty				
General/Family Practice	36.0	25.0	25.0	15.2
Medical Specialties	25.0	15.7	11.9	17.2
Surgical Specialties	32.6	23.1	14.3	20.9

The information in Table 2 does not reflect the overall share of physicians practicing defensive medicine. This is because the figures do not include physicians who practiced the same amount of defensive medicine in 1984 as they had in the past. However, information was available on the percent of physicians engaging in defensive medicine prior to 1984. This information is presented in Table 3 along with the percent of physicians who chose to increase the level of defensive medicine, or adopt defensive medicine measures for the first time, in 1984. While it is still not possible to ascertain precisely how many physicians engaged in some form of defensive medicine in 1984 from this information, it is apparent that the practice is widespread.

Table 3
PERCENT OF PHYSICIANS ADOPTING DEFENSIVE MEDICINE MEASURES

	Percent of Physicians	
	*Prior to 1984**	*1984***
Maintaining more detailed records	56.9%	31.0
Prescribing more tests or treatment procedures	43.0	20.0
Increasing time spent with patients	35.9	17.0
Increasing follow-up visits	–	1.70

*SOURCE: 3rd Quarter 1983 survey of the Socioeconomic Monitoring System.
**1984 figures represent physicians who increased their level of defensive medicine or adopted defensive measures for the first time.

Changes in Professional Liability Premiums and the Cost of Litigation

Increases in the rate of claims have been accompanied by increases in professional liability premiums. Preliminary figures on 1984 average premiums indicate that they have increased 11% over 1983 ($7,100 to $7,900). Additional information on 1984 premiums is being collected in the 2nd quarter 1985 SMS survey. Therefore, the final figures on 1984 premiums may reflect some adjustment of the preliminary figure given here.

In addition to paying higher insurance premiums, physicians can also incur litigation costs in the event of a claim. Among physicians having at least one claim filed against them in the last five years, 13.6% hired a lawyer in addition to that provided by their insurance company at an average cost of $9,100. Another cost associated with claims relates to time physicians lose from their practices. In the past five years, physicians lost an average of 2.7 days per claim due to time spent in court appearances and meetings with attorneys.

Month in Washington

(continued from page 474)

* * * *

Health Manpower ... Continued?

Rejecting President Reagan's contention that health manpower programs no longer warrant federal support, the House Commerce Committee last month approved bills extending programs the President proposed to abolish.

The programs include the health professions training assistance, nurse training programs, and the National Health Service Corps reauthorizatons which were vetoed by the President last fall and eliminated in his fiscal 1986 budget on grounds that the U.S. already has a surplus of physicians and an adequate supply of nurses.

The committee also approved a bill continuing assistance to community and migrant health centers which the President had proposed to put into a block grant along with black lung disease programs. New federal support of HMOs would be eliminated.

Approved by a convincing 17/6 vote, the health professions bill (HR-2410) in fiscal 1986 would fund physician and other health professionals at their 1985 level of $141 million. Inflation adjustments would be authorized in 1987 and 1988.

Other bills approved by the committee are:

- HR-2418 which authorizes $1.3 billion over the next three fiscal years for community health centers and $167 million for migrant health centers. HMO aid would be phased out as current grants expire.

- HR-2237 which funds the National Health Service Corps field service at $75 million in each of the next three years and provides "such sums as necessary" to award 1175 new scholarships over the next three years.

- HR-2370 which funds nurse training programs at the current level of about $50 million in fiscal 1986. Funds would increase by 5% in 1987 and again in 1988.

* * * *

GME Issue Heating Up In Congress

Newly proposed regulations to freeze Medicare support of direct costs of graduate medical education for a year could prove short-lived if Congress acts on either of two recently-introduced legislative alternatives.

The regulations, which were published in the Federal Register May 21, would implement one of the President's budget proposals and would save an estimated $145 million in fiscal 1986. HCFA proposes a one-year freeze, but requests comments on the advisability of continuing the freeze in future years.

The comment period on the regulations runs until June 20 but the regulation would be implemented on July 1, leaving an extremely tight time frame for assessing and incorporating any comments.

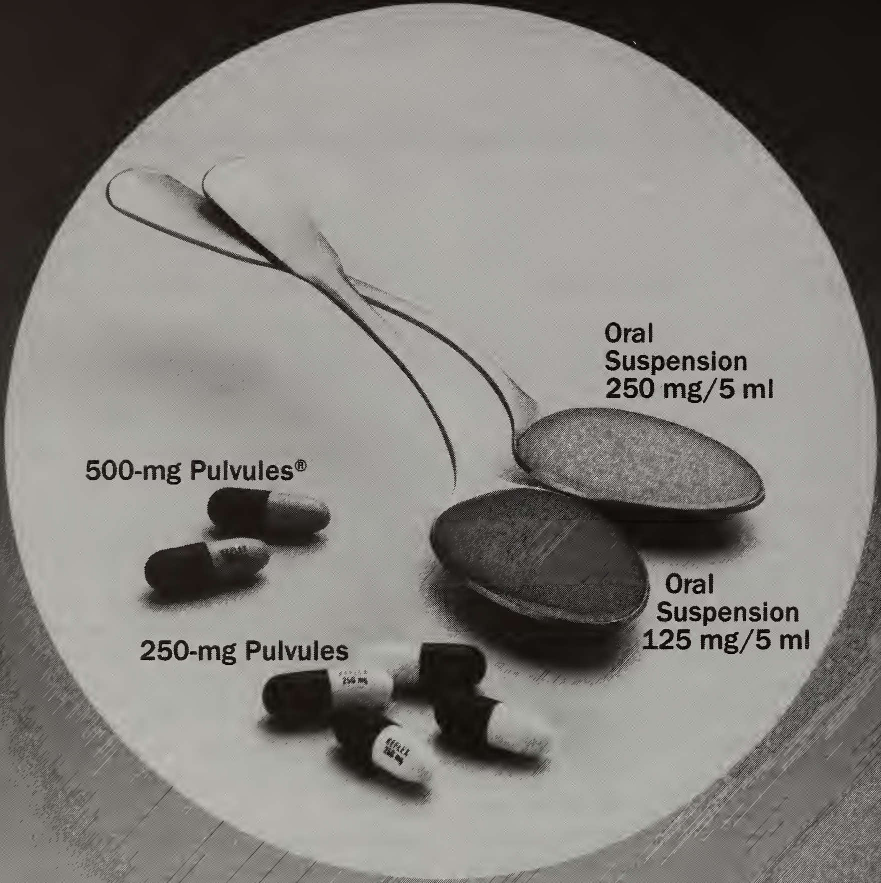
Meanwhile, legislators are moving ahead with their own plans to reform Medicare support of direct medical education costs.

In the Senate, Sens. Robert Dole (R-KS), and Dave Durenberger (R-MN) and Lloyd Bentsen (D-TX) have introduced legislation that would freeze these payments for a year, would limit support to five years per student, and eliminate support for foreign medical graduates who are not U.S. citizens.

In the House, Rep. Ralph Regula (R-OH) is sponsoring a plan that would replace the current direct medical education cost pass-through with grants to hospitals. Payments would be capped at $1.015 billion in fiscal 1986 with future increases tied to the increase in the consumer price index.

A formula based on the proportion of residents and Medicare patients at the hospital would be used to determine the payments to individual institutions. Payments would be adjusted for increases of up to 10% in the institution's training program but penalties would be imposed when the increases exceeded 10%.

Easy To Take



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The President's Page

20/20 Vision

Restructuring of the Medical Care system is presently underway, and it will take time to evaluate fully the impact of these changes on the doctor-patient relationship. The development of a specific forecast for the future environment of medicine is difficult.

Cost pressures are the fundamental force which are causing the evolution of change. The Federal government continues to intervene. The business world and Third Parties will overly attempt to influence how medicine is practiced. Consumers will be less passive. Hospitals will enter the primary care market. The Non-Federal, private fee-for-service practitioner will have to compete with all the major participatory forces. The economics of care may very well become a detrimental influence in making medical decisions. The public must be informed and educated on all related health matters!

"Trend may not be necessarily fate." The fate of our present standard of care, however, is directly related to these trends. During the coming months, many unexpected divisions and alliances may occur between physicians. The intensity of economic competition will grow because of the increased supply of physicians and health personnel. This will lead to points of dissension and disagreement in problems of access, privileges, manpower issues, issues of quality, conflicts of interest, competition between physicians and hospitals. The hazards of a divided membership are obvious. Therefore, in the ever-changing unpredictable environment of medicine, the existence of an organized, unified, professional body of physicians has never been more essential in order to preserve a point of reference and a position of strength. Unity will only be achieved, however, when the existing membership actively participates in support of their own personal ideals and principles along with the corporate standard and common cause of the Connecticut State Medical Society.

With the sense of mounting despair and uncertainty in the minds of the practicing physicians in the State, it will be imperative for the leadership of the Society to monitor the concerns and desires of the membership on an on-going basis. I look upon the coming year as one of increased communication with the membership on all issues which have a bearing on patient care.

In addition to maintaining an increased laison with the members of the Society, it is equally imperative to educate the public. The majority of the public is completely unaware of the changes occurring in the environment of medicine. Moreover, they are not cognizant of the consequences of the implementation of these changes on their potential relationship with their *hospital* and their *doctor.* Heretofore, we have been busily caring for our patients while not having time during these visitations to inform the public of our increasing concerns over the present day forces which are threatening to destroy our relationship with them.

The time has come for each individual member to become a vocal part of our public relations program. Leadership in our Society is vested not only in our elected officials. Leadership begins with each member of the Society. Each of us is a potential leader. Each of us has an opportunity to effect change. It is time for us to meet the public in order to neutralize their skepticism and criticism. Decision makers are the public. Public opinion determines Legislation. We must establish a foundation of support for future reference and enlistment. Physicians still enjoy the confidence of the majority of the public. We still have the opportunity to reverse the disintegration of that confidence.

In order to improve our public image, I propose that the Society reinforce an aggressive, on-going informative program of communication with our membership. We cannot become individual leaders without the facts.

Our Public Affairs Committee is poised to initiate a well devised novel program in the near future which will be activated through your offices. I ask you to endorse the concept and give full support to the program.

Finally, I propose that a Leadership Program be established immediately based on County participation in order to develop an informed speakers panel which will take our message to the public in a well organized, concerted, active, on-going, energetic, educational program in a live one-on-one basis.

We must remind ourselves that nothing is worse for people than to lose aim or a sense of direction. Progress comes through improving or outdoing what has been done before. We must turn adversity into advantage!

The Medicare Program was initiated twenty years ago, and we are aware of its consequences. The question arises as to how the present day forces will affect patient care in the next twenty years. We must develop 20/20 vision and control change with a steadfast loyalty to the individual patient!

William A. Whalen, M.D.
President

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Reflections on Medicine

The History Seminar

ROBERT U. MASSEY, M.D.

Three of us who were responsible for teaching the student elective seminar in the history of American medicine recently finished reading the student papers and then conducted our own *post-mortem* on the course. As had been true in the past, the papers ranged from good to excellent; each student had done a small piece of historical research using both primary and secondary sources, and we all learned from their presentations in class, the faculty most of all because we got to read their papers.

Our educational objectives in this seminar are modest enough; we know that it is a refreshing interlude for students who are working their way through the difficult first year of the basic sciences; we hope they enjoy it, as the humanities should be enjoyed, and that those who have an interest in history derive some intellectual satisfaction from the work. We would like them to acquire some feeling for how medicine got here in the first place; how medicine, the science of human biology, and modern technology got together in the last hundred years to create the enterprise to which they have determined to devote their lives; how the history of medicine and science are essential for understanding the present as well as the past, and for providing some reasonable guesses about the future. For a few, the seminar may be the beginning of a life-long interest in the history of medicine.

Knowing that this may be our only chance, we do what teachers are most often tempted to do: we tend to talk too much, we attempt to tell too much, and, taking pains to leave nothing out, we skim superficially over more dates, names, and discoveries than anyone could possibly remember or have use for.

Not surprisingly, the students said that they would appreciate more reading assignments. Someone once observed that the need for the lecture was remarkably diminished when Gutenberg began printing in Mainz with moveable type; we seem to have forgotten that, but everytime that reform in medical education is in the air, the lecture comes under attack and a few hours are trimmed away. So it should be with history.

What history should be covered? The temptation is to begin with primitive medicine, start naming dates and names beginning with Imhotep, and finish with a lecture on DeVries's implantation of the artificial heart or with a review of our notion of the risks of turning our hospitals and clinics over to investor-owned profit-making corporations. Rather than offering a seminar on the history of medicine, we should advise our students to read Paul Starr's *The Social Transformation of American Medicine.*

What is needed is the background of a simpler time to show the interrelationships of religion, values, politics, law, economics, technology, and epidemiology with the science and the art of medical practice. That probably may be managed best with the Greek city-states of the fifth century B.C.; another choice might be 17th century Europe. Everything else may then be skipped until we get to the last hundred years or so. In Connecticut we might begin a little earlier, taking in William Beaumont and Horace Wells.

The aim is to help the students to see the present and maybe a little of the future from the standpoint of history, to think of scientific and social events in an historical way; to feel in their bones that medicine and the human enterprise are inseparably bound together; and that the way we affect the future depends ultimately upon what we value.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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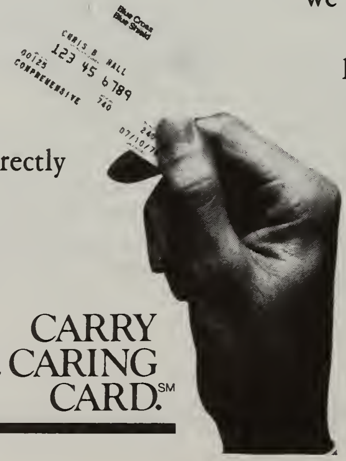

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The Journal of the Connecticut State Medical Society
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Pursuit of Excellence

Following demobilization after World War II, St. Vincent's was the beneficiary of waves of well-trained, combat-experienced physicians from all backgrounds, hoping to establish medical practices in a hospital sorely in need of new, enthusiastic men anxious to get on with their civilian lives. Generational gaps in personnel permitted immediate recruitment to all of the major services. Recognition of the need to affiliate with well-established post graduate training led to the establishment of a consultative and advisory agreement with the New York University Medical School Regional Hospital Plan. Key to this enlightened approach was the appointment of Dr. Wm. H. Curley, Jr. as the first director of Medical Education at St. Vincent's Hospital. He accepted this as a personal challenge and recruited other physicians with similar interests. They first established a meaningful, balanced rotating internship. From this grew fully qualified residencies in Surgery and Medicine. Initially, all of the staff members were in private practice, contributing their patients and time freely. The goals and rewards could be summarized as continued, improved patient care and physician expertise. I chose to use the phrase, "Pursuit of Excellence" because it is a never ending journey with new fellow travelers along the road, freshening the approaches and opening new side roads to places previously unexplored.

St. Vincent's Hospital has been razed. St. Vincent's Medical Center has been constructed. The physical plant reflects the many changes that have resulted from the original decision to provide the highest quality of care in a modern community hospital. Every administrator has enthusiastically supported this goal by providing the facilities and funding. A new, more intimate affiliation was established with Yale University Medical School. Full-time chiefs in the departments of Medicine, Surgery, Psychiatry, Pediatrics and Emergency Care have joined the traditional full-time chiefs to more efficiently direct the educational programs.

The community at large has been rewarded in many ways by this ongoing hospital effort. As only one example, many of the nurses and technologists trained at St. Vincent's (Hospital-Medical Center) staff hospitals locally and state-wide.

S.V.M.C., at one time, a small hospital with a small general staff, has grown into an affiliated community hospital, fully staffed, capable of treating the full range of problems in medicine and surgery. From modest beginnings, a litany of progressive steps have been capped by some of the finest departments in the state and most recently the fully supported open heart program. I'd be remiss if I didn't specifically mention the departments of Pathology, Radiology, Medicine, Anesthesiology, Surgery, and Psychiatry.

We are proud of many innovations at St. Vincent's Medical Center, but one has found popularity nation-wide. Same-day surgery started at S.V.M.C. in the early 50's and today represents approximately 35% of all surgery performed in our operating suites.

Many of us recognize that opportunities for research, teaching and treating are no longer unique to university centers, but can be fully satisfied in an appropriate affiliated community hospital setting. The educational committee of S.V.M.C. has decided that the growing census of problems related to our senior citizens would serve as our focus of attention for this special issue of *Connecticut Medicine.*

Michael A. Dean, M.D.,
Guest Editor

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

Chief, Division of General Surgery, St. Vincent's Medical Center, Bridgeport, CT. Assistant Clinical Professor of Surgery, Yale University School of Medicine.

The Wennberg Lesson

Dr. Wennberg's testimony and research are making an important contribution to our understanding of health care delivery in this country. Too often reformers attack the management of hospitals in the name of cost containment, completely unaware that they are aiming at the wrong target. While such misdirection is based upon a lack of understanding, ignorance has seldom muted the reformers' enthusiasm. The energy and money expended by the Connecticut Business and Industry Association (CBIA), the Insurance Association of Connecticut (IAC) and the Commission on Hospitals and Health Care (CHHC) to further constrict hospitals under the new All-Payor regulations is the latest example of misdirection. Their efforts continued the uninformed claim that the problem with health system costs is inefficient hospitals. While improvements in performance must be sought, Dr. Wennberg's research reveals that the most important aspect of cost containment is physician practice patterns.

Physicians want to practice good medicine. No doctor wants to treat his patients in a way that is contrary to professional standards or is wasteful of resources. However, Dr. Wennberg demonstrates that the lack of standards generates practice styles that are variable and inefficient. However, if information is supplied, most physicians are willing to modify practice patterns to ones which are both clinically efficacious and cost effective. This requires the development of programs to collect and report information which will increase understanding and, thereby, allow physicians to draw rational conclusions regarding clinical practices.

For years, Connecticut hospitals have argued that physician practice patterns in this State are conservative compared to other areas. This is reflected in the low number of beds and hospital admissions and high occupancy rates. Even so, early experience under prospective payment is diminishing the demand for inpatient services, demonstrating what happens when physicians are provided information which enables them to understand the impact their clinical decisions have on hospital performance.

Restricting admissions and doing more for patients in the ambulatory setting, and reducing lengths of stay while utilizing home care or other lower cost alternatives makes clinical and economic sense. These actions are occurring because a fixed price payment system has different incentives than a retrospective cost based system. Hospitals are collecting and disseminating data which enable physicians to compare their practice patterns by DRG with their peers'. Such information and knowledge are changing resource consumption more significantly than has a decade of regulation.

I urge the CHHC, the CBIA and the IAC to study the Wennberg findings, paying particular attention to comparisons of Connecticut with other areas. They should commission studies which will demonstrate whether or not Connecticut has problems which warrant concern and, if so, what specific areas need attention. This would enable a targeted attack to be mounted against an identified problem, rather than the shotgun approach that has been used, and would be a more constructive use of their resources.

Secondly, I urge that the Connecticut State Medical Society initiate studies, either on its own or by contract with clinicians and epidemiologists at universities, which evaluate alternative diagnostic and therapeutic interventions. Unless the profession can develop parameters of concurrence, regulators and payers will assume that the least costly intervention is the most acceptable. If there is no demonstrable outcome difference, low cost should prevail. If there is a clinical difference, we must be able to identify it.

Connecticut citizens are blessed with well-trained physicians and well-managed hospitals. Rather than simply assuming that costs are too high, we should compare our performance to others in both cost and outcome terms and determine if a problem exists. If so, problems will be solved more effectively by proper incentives and education, not by regulation.

It is unfortunate that the Wennberg lesson was not available before the regulatory model was implemented. Physicians and hospital managers have a commitment to serving their patients, and they will do so cost-effectively if they understand that it is also clinically acceptable.

C. Thomas Smith

President,
Yale New Haven Hospital, New Haven, CT

Final PRO Rules Issued

Four long-awaited final PRO rules were finally published on April 17. The four rules concern the confidentiality of PRO information, sanctions against practitioners and providers, reconsiderations and appeals of PRO denial determinations and PRO review functions. The rules become effective on May 17.

Confidentiality of PRO Information—The confidentiality rule governs the acquisition, protection and disclosure of information obtained or generated by PROs. The most controversial issues raised by this rule involve the disclosure of information that identifies specific practitioners and institutions. The rule protects practitioner-identified information from general public disclosure. HCFA concurred with the strong concern voiced by the AMA and others that such information could be misleading and result in significant damage to the reputations of many physicians.

The final rule, however, requires disclosure of hospital specific information. It provides that PROs must disclose upon request aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers. Information showing the mortality rate by hospital for different types of surgery, the number of patients who develop postoperative infections, and the average length of hospital stays will be available to the public. The final rule also permits PROs to disclose to the public their interpretations and generalizations concerning the quality of care at particular hospitals.

—*AMA Legislative Roundup*, April 26, 1985

IN MEMORIAM

BLOSSOM, DUDLEY B., Columbia College of Physicians and Surgeons, 1938. Dr. Blossom was a radiologist in the Fairfield County area since 1947. Former chief of radiology at Greenwich Hospital he helped develop a one-man X-ray department into a sophisticated department of radiology. After retiring in 1972, Dr. Blossom was named to the hospital's honorary staff. Dr. Blossom was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 12, 1985 at the age of 78.

CUNNINGHAM, ROBERT D.M., Yale University School of Medicine, 1930. Dr. Cunningham was a pediatrician in the Fairfield County area since 1930. Before his retirement, he was president of the Stamford Medical Society in 1965 and associate pediatrician in chief in Stamford in 1966 and 1967. Dr. Cunningham was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died May 23, 1985 at the age of 80.

FINCKE, C. LOUIS, Harvard Medical School, 1928. Dr. Fincke was an internist in the Fairfield County area since 1931. He was Chief Emeritus of Stamford Hospital and St. Joseph's Hospital. Dr. Fincke was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 4, 1985 at the age of 83.

JOHNSON, PAUL R., Tufts Medical School, 1932. Dr. Johnson was an obstetrician and gynecologist in the Hartford County area since 1941, retiring in 1980. He served on the staff of Hartford Hospital. Dr. Johnson was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died April 9, 1985 at the age of 80.

LYNCH, VINCENT A., Jefferson University School of Medicine, 1938. Dr. Lynch was an internist in the Fairfield County area since 1946. He was the chief of medicine at St. Vincent's Medical Center from 1951 to 1970, the first medical director of St. Joseph's Manor from 1960 to 1975, the president of the Bridgeport Medical Association as well as the president of St. Vincent's medical staff. In 1963, Pope John XXIII appointed Dr. Lynch to the Papal Order of the Knights of St. Gregory for his notable accomplishments for charity service. Dr. Lynch was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died May 20, 1985 at the age of 72.

MACKAY, WILLIAM D., Indiana State University School of Medicine, 1928. Dr. MacKay was an internist in the Litchfield County area since 1942. He practiced medicine in the Westchester County, NY area before moving his practice to Connecticut. Dr. MacKay was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 9, 1985 at the age of 89.

PASETTO, EDO, University of Vermont School of Medicine, 1936. Dr. Pasetto was a radiologist in the New Haven County area since 1939. He was a member of the radiology staff at Waterbury Hospital and was also affiliated with the Middlebury Orthopedic Group. Dr. Pasetto was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 3, 1985 at the age of 74.

TAYLOR, ROBERT M., George Washington University School of Medicine, 1922. Dr. Taylor was a general practitioner in the New Haven County area since 1922. He served as medical examiner for the town of East Haven from 1930 to 1970 and was the town's health director from 1930 to 1972, when the East Shore Health District was formed. Dr. Taylor was assistant medical examiner for New Haven from 1930 to 1965. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 13, 1985 at the age of 87.

VERSTANDIG, CHARLES C., University of Tennessee College of Medicine, 1939. Dr. Verstandig was a diagnostic radiologist in the New Haven County area since 1944. He began in radiology when it was a new science and worked to promote it in the United States and abroad. Dr. Verstandig helped found the Hill and Fair Haven health centers when he was president of the New Haven County Medical Association in the late 1960s and donated monies for the X-ray suite of the Masonic Hospital. In 1983 he was awarded the Presidential Citation of the American Association of Homes for the Aging. He also won the Distinguished Service Award of the American Medical Association. At the time of his death, he was radiological consultant for the U.S. Military Entrance Processing Station in New Haven, the Masonic Hospital in Wallingford and the Radiological Institute in New Haven. Dr. Verstandig was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 1, 1985 at the age of 76.

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Opportunity available in our 220-bed community hospital with an active prehospital care program for a full time emergency medicine trained or practice tract prepared physician. Our six full time physician staffed department has a volume of 28,000 visits annually. Excellent benefits and competitive salary are offered. Please send CV to Patricia C. Kuszler, M.D., Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT 06450.

Farmington Valley, CT. Full time emergency physician needed immediately for walk-in treatment center. Opportunity for full partnership. Write CSMS, c/o EM/JR.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

FAMILY PRACTICE

Board certified or eligible residency trained family physician wanted to associate with same in a growing town of 20,000 in the foothills of the Connecticut Berkshires. Established, growing practice—salaried first year; full partnership in second year. No OB. Send CV to P. Anderson, M.D., One Old Park Lane, New Milford, CT 06776.

Family physician to join board certified residency trained family practitioner in a growing, two office practice in Guilford or Essex on the shoreline. Beautiful area; enjoyable life style; excellent schools. Great opportunity for professional and personal satisfaction. Will consider part-time. Reply to, Alan Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

INSTITUTIONAL MEDICINE

JCAH-Accredited 350-bed State Hospital seeks the services of a board eligible physician with experience or interest in Respiratory Therapy and a willingness to participate in limited administrative functions. Work week of five days, 35 hours with liberal State fringe benefits. Send C.V. to R.J. Cavalieri, M.D., Chief of Medicine, Veterans Home and Hospital, 287 West St., Rocky Hill, CT 06067.

Walk-In Medical Services is seeking full and part time physicians to work in a convenience medical facility in Orange, CT. FAM. PRAC/IM preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Internist. B.C. with some cardiologic training for full-time position with large Southern Connecticut company. Outstanding career opportunity for ambitious individual in occupational and corporate medicine. Reply to CSMS, Box IM/SSS.

Internist—University-based HMO seeks inquiries and applications for staff positions. Competitive salary and benefits programs. Contact, Medical Director, Yale University Health Services, 17 Hillhouse Ave., New Haven, CT 06520 (Tel. 203-436-8433).

PEDIATRICS

Pediatrician—Board eligible or certified to join group of three pediatricians in coastal Connecticut close to New York City. Competitive salary and benefits with early partnership. Reply to: CSMS, PED/RR.

BE/BC pediatrician wanted to join practice of three pediatricians and PNP in Middletown. Excellent salary and fringe benefits leading to full association. 350 bed community hospital with Level II nursery and F.P. residency program. Please send resume to Middlesex Pediatric Assoc., P.C., 80 South Main St., Middletown, CT 06457.

PRACTICE FOR SALE

Ophthalmology practice for sale. Active surgical practice in eastern Connecticut. Modern office, solo but associated with town's other ophthalmologist. Moving for family reasons. Terms, negotiable. Send CV to Samuel Masters, M.D., P.O. Box 16, Willimantic, CT 06226.

General, active surgical practice for sale in southern Connecticut. Medium-sized city. Well equipped office including fully equipped minor surgical suite. Available July 1, 1985. Reply to CSMS, c/o SALE/BB.

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

PRIMARY CARE

Primary Care Physicians, BC/BE, needed to join expanding Walk-In Medical Center Group in central Connecticut. Full or part-time positions available. Compensation package includes competitive salary, malpractice insurance, and profit sharing opportunity. Stimulating work experience in a comfortable setting with flexible scheduling. Send C.V. to: PhysicianCare, 28 Main Street, East Hartford, Ct., 06118, or call (203) 569-8644.

Physicians—Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

Southern CT area/Walk-In Medical Center seeks licensed physicians. Full and part time positions available days, evenings and weekends. Competitive salary. Please respond to CSMS, GP/JS.

PSYCHIATRY

Consulting psychiatrist for community-oriented psychosocial rehabilitation agency. Licensed required. Psychiatrists needed to provide three hours, every other week of consultation services at a facility serving the greater Norwich area. Clientele consists of poor, chronically mentally ill adults. Send inquiries to David Burnett, Executive Director, Reliance House, Inc., 132 Broadway, Norwich, CT 06360.

Child Psychiatrist needed for full to part-time, in greater Hartford area, to join a well established office and hospital practice. Reply to CSMS, PSY/MN.

RADIOLOGY

Part-time radiologist, board eligible or certified for private office practice in greater Hartford area. Please send CV to CSMS, RAD/CC.

Radiologist wanted part-time for general diagnostic radiology in private office practice in Waterbury area. All replies confidential. Write CSMS c/o RAD/AA.

Hospital based general diagnostic radiologist with special interest and training in invasive radiology is being recruited by six man radiology group for 100 plus general hospital in Northeastern Connecticut. Individual must have depth of experience necessary to initiate and manage interventional procedure program. Hospital offers nuclear medicine, ultrasound and mobile CT scan unit. Send curriculum vitae to Jonathan Berger, M.D., 142 Echo Dr., Vernon, CT 06066.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

Immediately available. Age 31. AB elig. MD, G.S. Medical College; Int., Flushing Hospital of Medical Center, NY; Res., Albert-Einstein College of Medicine, NY; Fellowship, Maimonides Medical Center, NY. Prefers solo, group or associate type practice. Write, Vasant Chheda, M.D., 950 49th St., Apt. 8K, Brooklyn, NY 11219.

July '85. Age 39. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Bangalore Medical College, India; Res., Cheettenham General Hospital, Dryburn Hospital and Birmingham Accident Hospital, U.K.; Fellowship, Maimonides Medical Center, Brooklyn, NY. Interested in OB Anesthesia, Pediatric Anesthesia and General Surgery with a group, associate or institutional type practice. Write, Yellagondahalli Janardhan, M.D., Apt. 108, 34 Minebrook Rd., Edison, NY 08820.

Aug. '85. Age 33. Presently in practice. FLEX. AB elig. MD, Far Eastern University, Philippines; Int. and Res., State University of NY, Downstate Medical Center; Fellowship, State University of NY (OB and PED Anesthesia). Prefers solo or group type practice. Write, Frederick D. Moser, M.D., 143-47 Barclay Ave., Flushing, NY 11355.

FAMILY PRACTICE

Aug. '86. Age 28. Nat'l bds. AB elig. MD, State University of New York at Buffalo; Int. and Res., University of Maryland. Prefers group, associate, institutional, or industrial in a small to medium-sized community. Particularly interested in a coastal community but will consider all offers. Write, Anthony E. Turiano, M.D., 1411 West 37th St., Baltimore, MD 21211.

July '86. Age 30. FLEX. MD, Autonomous Univ. of Guadalajara, Mexico; Int., (Fifth Pathway) New Rochelle Hospital Medical Center, New Rochelle, NY; Res., The Williamsport Hospital, Williamsport, PA. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Francis C. Imbarrato, M.D., 505 Hawthorne Ave., Williamsport, PA 17701

INTERNAL MEDICINE

GASTROENTEROLOGY. Oct. '85. Presently in practice. Nat'l bds. AB cert.(IM); AB elig. (GI). MD, University of South Dakota; Int., Res., and Fellowship, George Washington University. No preference to size or type of practice. Write, Howard L. Tice, M.D., 3260 Lovers Lane, Fayetteville, AK 72701.

PRIMARY CARE. April '86. Age 32. FLEX. AB elig. MD, University of Rome, Int., Long Island College Hospital; Res., Illinois Masonic Medical Center. Desires group or associate type practie in a medium to large-sized community. Write, Eli R. Goldner, M.D., 2841 W. Rosemont, Chicago, IL 60659.

OBSTETRICS AND GYNECOLOGY

April '85. Age 30. Presently in practice. AB elig. MD, NY Medical College; Int. and Res., NY University/Bellevue Medical Center. Primarily interested in a group practice in a medium-sized community. Write, Andrew R. Herzog, M.D., 229 Haven Rd., Franklin Lakes, NJ 07417.

OTOLARYNGOLOGY

July '85. Licenced in Connecticut. Age 33. Nat'l bds. AB cert. MD, New York University; Int., University of California, San Diego; Res., Yale University Medical Center; Fellowship, UCLA Prefers group or associate type practice in a large-sized community. Write, CSMS, IM/OTO.

PATHOLOGY

Aug. '85. Age 32. Nat'l bds. AB elig. MD, New York Medical College; Int., Brookdale Hospital, Brooklyn, NY; Res. St. Luke's Hospital, New York; Fellowship, Montefiore Hospital, Bronx, NY (Cytology). Prefers associate or institutional type practice. Write, Janet Schneller, M.D., 174 E. 206 St., Bronx, NY 10458.

PEDIATRICS

Immediately available. FLEX. AB cert. M.B.B.S., Medical College of Baroda, Baroda, India. Int., Medical College of Baroda; Res., Waterbury Hospital, Waterbury, CT and University of Medicine & Dentistry of NJ, Newark, NJ. Prefers solo, institutional or industrial type of practice. Write, Kirti M. Vora, M.D., 41 E. White Terrace, Nutley, NJ 07110.

PEDIATRIC PULMONARY. Sept. '85. Age 36. Presently in a clinical academic position. Nat'l bds. AB cert. (PED); AB elig. (PED. PUL). MD, Jefferson Medical College; Int., Pensacola Educational Program; Res., Scared Heart Children's Hospital, Pensacola, FL; Fellowship, University of Florida. Prefers group practice with at least two to three other Pediatricians. Teaching responsibilities welcome. Write, John S. Liggett, Jr., M.D., 7306 Hollyoak Drive, Tyler, TX 75703.

RADIOLOGY

NUCLEAR MEDICINE. July '85. Age 34. Nat'l bds. AB elig. MD, Albert Einstein College of Medicine, NY; Int., Bronx Municipal Hospital Center, NY; Res., Mallinckrodt Institute of Radiology, St. Louis, MO. Prefers group, associate or institutional type practice in a large-sized community. Write, William Ganz, M.D., 7476 Ahern Court, University City, MO. 63110.

SURGERY

GENERAL. July '85. Age 30. Nat'l bds. AB elig. MD, St. Louis University School of Medicine; Int. and Res., St. Louis University Group Hospitals. Prefers group or associate type practice in a medium to large-sized community. Write Dan S. Reiner, M.D., 7028 Waterman Ave., St. Louis, MO 63130.

A Medical Helicopter Transportation System for Connecticut

LENWORTH M. JACOBS, M.D., M.P.H., FACS,
BARBARA BENNETT JACOBS, R.N., BSN, EMT-P, CEN
AND ROBERT SCHWARTZ, M.D.

The Injury Problem

The use of helicopters is a method that was designed initially to respond to the need for expeditious transport of trauma victims to definitive care facilities. Trauma or injuries are the leading cause of death for those persons under the age of 37. In 1983, there were 91,000 accidental deaths and 9,400,000 disabling injuries.[1] Motor vehicle accidents account for 51.5% of the deaths. The cost of medical care for those injured in alcohol-related motor vehicle accidents was $434-483 million.[2] It is estimated that care of trauma victims cost $61 billion in 1982.[3] Because the highest incidence of trauma occurs in the adolescent and young adult population, the number of productive life-years lost is dramatic.

As a major national epidemic, trauma is a substantial problem for the public health as well as private health sectors.[4] Persons who have sustained significant injuries require specialized surgical intervention in terms of diagnosis, treatment, monitoring, and in some circumstances operative treatment. For comprehensive care of trauma patients, a systems approach has been designed and suggested as the optimum approach to reduce mortality and morbidity from injuries already sustained.[5-16] Some of the components of this system include; 1) easy access to the pre-hospital system; 2) a communication system with the technology to connect providers at the scene with trauma physician-specialists in trauma centers; 3) on scene resuscitation; 4) transport to a designated hospital that is equipped and capable of rendering immediate and comprehensive definitive care. Rehabilitation is an integral part of the therapeutic regimen as the goal of trauma management is to return the patient to his/her pre-injury status.

The Injury Process

The injury or trauma process is a multifaceted one with causes, mechanisms, influences, and control strategies. The Haddon matrix which depicts the factors involved in an injury (person, vehicle, environment) and the phases of an injury (pre-event, event, postevent results) is a useful one to analyze the injury process.[17] Injury control theories and practices can be identified in various positions of the matrix along with the influences that are characteristic of each phase and factor. Environmental factors, such as objects on roadways like trees, poles, and roadsigns are associated with the event phase. The factor is the environment not the individual. Frequently, individual behavior is blamed for accidents such as considering the human factor in the pre-event phase and identifying alcohol intake as a possible influence. The injury problem however, is more complex and altering human behavior is not the only issue. Injury control and accident prevention are important research topics; however, presently the need is still there to consider the environmental factors associated with the post-event phase, ie. comprehensive emergency medical services (EMS) and transport/treatment modalities to manage the patient after the injury has been sustained.

One such post-event system to respond to trauma victims, utilizes a helicopter for quick response to the scene and intensively monitored transport to a trauma center.

History of the Use of Helicopters for Medical Transportation

The use of the helicopter as a component of a trauma care system began in the Korean War.[18] The military

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LENWORTH M. JACOBS, M.D., M.P.H., FACS, Director, Trauma Program and Emergency Medical Services, Hartford Hospital; Associate Professor of Surgery, University of Connecticut Medical School. BARBARA BENNETT JACOBS, R.N., BSN, EMT-P, CEN, Flight Nursing Educational Consultant, Department of Education, Hartford Hospital. ROBERT SCHWARTZ, M.D., Trauma Fellow, Department of Surgery, Hartford Hospital.

discovered that bypassing Battalion Aid Stations and transporting injured soldiers directly to Mobile Army Surgical Hospitals (MASH), often by helicopter, reduced the time from injury to definitive care. During World War II it took from six to twelve hours to accomplish this transport while in Korea the time was reduced to two to four hours. Mortality decreased from 5.8% in World War II to 2.4% in Korea.[18]

In Vietnam, this concept was expanded to the use of larger, faster helicopters that not only transported patients, but also carried trained medical corpsmen with advanced life support (ALS) skills and equipment to the battle scene. The wounded were then transported to hospitals providing definitive care. These facilities had all the necessary equipment and surgeons immediately available for operative intervention. The time from injury to definitive care was sixty-five (65) minutes and the mortality rate dropped to 1.7%.[19,20]

In West Germany this concept was translated into civilian practice. In this system, transport of a patient from the scene to a trauma center can be accomplished in fifteen (15) minutes. All West German trauma centers have access to hospital-based medical helicopters with ALS personnel aboard including physicians.[21,22]

In 1972, the National Highway Traffic Safety Administration (NHTSA) of the Department of Transportation published a report on medical helicopters, *Helicopters in Emergency Medical Services NHTSA Experience to Date.*[23] The document reported the results of helicopter demonstration projects funded by NHTSA. Projects experienced the same difficulties—high operational costs, unsuitable helicopter designs, and little advantage over ground ambulances in urban areas. Improved helicopter design and hospital upgrading to handle trauma victims have contributed to the formation of integrated systems to respond immediately to a traumatized victim. At the time of these projects, systems were not organized and integration into the total EMS system was lacking.

With a few exceptions, most trauma centers were located in the inner cities, supported in part by municipalities and the centers had a large case mix of patients presenting with penetrating injuries secondary to civilian violence. Physicians in Denver, Colorado in 1973, recognized that the military model had applicability to civilian practice. St. Anthony's Hospital was the first hospital in the USA to implement a hospital-based, critical-care helicopter service. A major educational program was initiated to train first responders, emergency medical technicians, law enforcement and public safety personnel to recognize those patients who would most benefit from rapid resuscitation and transportation by air. A dedicated EMS communications center was established and all field personnel were instructed in use of telephones and/or radios to request dispatch of the helicopter.[24]

"Flight for Life" in Denver was the first hospital-owned and operated aerovac system staffed with medically trained personnel and was fully integrated into the Denver EMS system. After twelve years of operation, this service has transported over 25,000 patients and continues to be the national role-model.

First Generation Medical Air Transport Systems

The Denver system is an example of a successful first generation system. The helicopter was an impetus for the hospital to conduct extensive training of their physician and nursing personnel and to improve the physical layout to care for the increasing number of critically-ill patients. Immediate availability of intensive care beds, stocked blood banks, and sophisticated diagnostic capabilities, ie. angiography, and computerized-axial tomography were provided. In addition, specialty physicians including neurosurgeons and anesthesiologists were available to resuscitate and surgically intervene. This process was labor intensive and sustained significant operating costs. These costs, in the early years, were offset by the increased census of severely injured patients requiring sophisticated technology during the inpatient stay. The charges for the transportation of these patients were sometimes intentionally set below cost in order to be competitive with ground ambulance services.

There was an additional marketing effect which was not apparent until later in the developmental process. Other non-injured patients with elective problems began to select the hospital as their hospital for medical care as it was perceived that if the hospital could manage severely traumatized patients, it was quite likely that it was a "good" hospital for treatment of other medical problems. The original medical aerovac pioneers believed the system would save lives not only because of rapid transport but also because patients would receive comprehensive trauma center care. It was the dedication and commitment of the medical and administrative staffs that contributed towards the improvement in patient care not merely the procurement of a helicopter. The characteristics of a First Generation System are found in the pioneer programs in Denver,[24] Houston,[25] and Jacksonville; 1) use of a single-engine helicopter; 2) medical crews trained in ALS dedicated to helicopter service; 3) integration into the EMS system; 4) primarily serviced the owner hospital; 5) increased the owner hospital's bed occupancy rates; 6) inappropriate low service charge; cross-subsidization from other inpatient generated services to offset helicopter-charged revenue losses. The success and visibility of the first generation programs also made the helicopter market increase in intensity and competiveness. Coinciding with this was a decrease in the utilization of helicopters for offshore oil exploration. The scene was set for diversification by helicopter companies into the aeromedical industry.

The number of helicopter companies has increased from the original three in the early 1970s. Multiple new companies as well as numerous oil exploration and executive transport companies became more involved in the medical transportation field. There are now more than eighty hospital-based helicopter programs in the United States.

In some geographic areas, competing aeromedical transport programs existed. The mission of transporting only severely injured patients was diluted and the medical necessity for such transports was challenged. Additionally, regulatory health agencies became involved in the process. Since most of these programs were hospital-based and the capital expenditure was substantial, a Certificate of Need (CON) became a prerequisite for operation. This introduced the second phase of programs.

Second Generation Medical Air Transport Systems

In the early phases of the second generation programs, during the late 1970s, the regulatory agencies became concerned with identifying and quantifying the actual need vis-a-vis the ability to improve quality of care and increase survival of users. Quantitative evaluative processes were developed by groups in Omaha,[26] Boston, San Diego,[27] and Michigan. The Michigan experience identified injury-specific incidence rates for trauma, burns, spinal cord injuries, and neonatal crises as a prospective predictor of hospital utilization that showed correlation with operational reality.[28]

Health officials were concerned with the cost of the service yet it was not apparent that the belief existed that costs for the service should balance with revenues from it. The practice of charging for the service below the cost of what it took to operate it continued.

It was perceived that the imbalance between costs for operation and revenues received in return would be offset by patient revenues generated from the hospitalization fees of the more severely injured patients. In general, air-transported patients stayed an average of 5.7 days in the intensive care unit, an average of 19.3 days in the hospital and generated $10,500 in charges/patient.[29] Three additional characteristics were added to the first generation programs that identify the second generation programs; 1) certificate of need approval prior to operation; 2) quantitative research to predict the use of the service as part of the CON approval; 3) multiple missions for other than trauma patients, ie. neonates, cardiac patients.

Third Generation Medical Air Transport Systems

The third generation programs were initiated at the same time that rising hospital costs were becoming a major issue in the medical, public, and political arenas. In October, 1983, the government in an attempt to contain rapidly expanding health care costs, instituted a prospective reimbursement system for paying hospital-generated costs of Medicare patients based on a fixed rate of return according to the patients' diagnosis-related group (DRG).[30]

This legislation has had and will continue to have a profound effect on the manner in which American health care is delivered.[31,32] In essence, if a hospital can render care less expensively than for the sum of money with which it is prospectively reimbursed, that hospital can use the remaining money in ways that are beneficial to future patients. Conversely, if the care given costs more to deliver than the hospital is reimbursed, the hospital may have to decrease its operating costs in order to survive. This is particularly important to Connecticut since other health insurance carriers have expressed major interest in this type of reimbursement and potential for cost containment and improved hospital management. The DRG reimbursement process affects cross-subsidization since the hospital is reimbursed a fixed amount for each patient regardless of the costs incurred. Therefore, the fiscal management of helicopter programs sustained significant changes following the introduction of cost containment schemes and reimbursement strategies. The characteristics that make third generation programs different are; 1) use of twin-engined helicopters for safety, speed, and diversity of missions; 2) involvement of state regulatory agencies and external oversight committees in planning and operation of programs; 3) improved research strategies to test cost benefits and cost effectiveness; 4) multiple hospital involvement in transferring and receiving air-transported patients.

Hartford Hospital's new Helicopter Program for the state of Connecticut is one of the prototypes of a third generation aeromedical system. Other similar systems are in various phases of development in San Francisco and Boston.

The Hartford Hospital Helicopter Program

In West Germany, roadway mortality was reduced 25% from 16,000 in 1970 to 12,000 in 1981.[21,22] During this period a system of trauma centers and helicopter stations with fully-trained flight personnel who start resuscitation at the scene was implemented. This strategy for injury control is an example of dealing with the environmental post-event phase of the injury process. Of particular interest is that there is no speed limit on the West German autobahns. Experiences in West Germany have suggested that immediate advanced life support and rapid transportation by air to a fully staffed trauma receiving center is an effective way to reduce mortality from injuries once sustained.

In 1983, the State of Connecticut recorded 430 deaths from 104,503 motor vehicle accidents.[33] To prevent accidents, programs such as police programs to control speeding and to limit driving while under the influence of alcohol were instituted; this is an example of a strategy that deals with the human factor in the pre-event phase.

To respond to the trauma endemic, Hartford Hospital proposed a critical care helicopter service for the State and surrounding territory within a 150 mile radius. Staffing the helicopter are nurses trained in advanced cardiac and trauma life support and other medical interventions necessary to sustain life in the most critical patients.

The project is designed to contribute to the reduction in the number of deaths from trauma, cardiac arrest, burns, spinal cord injuries, and neonatal crises. The system has the capability to transfer critically ill patients from one hospital to another as well as from an accident scene to a trauma center. When an interhospital transfer is requested, the transferring physician caring for the patient, needs to contact the receiving physician; the helicopter can be requested for transport of any critical patient or for a patient at any level of severity who requires a special diagnostic or therapeutic procedure only available at a tertiary facility. The program is also available for medical disasters to transport expert medical teams to the scene of a disaster to augment the local disaster response as well as transport critical patients to an appropriate hospital.

The philosophy of this program in terms of patient destination is that as a community service, patients will be transported to any appropriate receiving center.

The State Office of Emergency Medical Services' which has the regulatory authority for overseeing this service, has developed criteria for hospitals who wish to receive helicopter-transported patients. It has also drafted guidelines regulating the operation of a critical helicopter transport service in Connecticut.

Finally, the state established an Oversight Committee with broad medical, community, and aeronautical representation to review the medical and aeronautical practices of the program.

The helicopter can be airborne with the medical crew within five minutes of notification and be able to access all hospitals, roadways, or other scenes where a safe landing site is identified. The program is operational 24 hours/day and all missions are under medical direction via radio to the Hartford Hospital Trauma Center.

The Certificate of Need Process

Because implementing a helicopter program is a major capital expenditure, Hartford Hospital submitted a CON in October of 1983. This lengthy and complex document was filed with the State of Connecticut's Commission on Hospitals and Health Care. The Commission decreed that since this was a service for the entire state it would have to be discussed and defended before each of the Health Service Agencies (HSA); this was done.

In keeping with the philosophy of providing a statewide service the program was discussed with multiple groups including; the Office of Emergency Medical Services of the State's Public Health Department, the Conference of Ambulatory Care Directors, the Emergency Department Directors of Connecticut, the American College of Surgeons' Committee on Trauma of Connecticut, the Connecticut Catholic Hospital Council, the Region IV Consortium of Hospitals, and many other interested groups.

Hartford Hospital operates close to capacity and increasing the bed occupancy, especially with severely-injured patients, was not the driving objective of the program. The mission is to respond to critically injured patients who require specialized resuscitation and immediate tertiary investigation and definitive treatment.

The CON process required that the program be financially independent and that the charges for the system would have to reflect the cost. In other words, the charge for each flight would be determined by dividing the number of flights per year into the annual operating budget. Reimbursement for an aeromedical transport is the responsibility of the patient and his/her insurance carrier. The hospital does not plan to undertake any fiscal screening prior to responding to any patient. Patients will receive the service, if needed, regardless of their ability to pay. Therefore, a "bad debt" factor is built into the cost of the program.

Approval of the program was given by each HSA and in February, 1985 the Commission on Hospitals and Health Care approved the CON.

Specialized Flight Nurse Training

Once the CON approval was granted, a comprehensive educational program for training the first flight nurses was initiated. It is anticipated that the majority of patients being transported, based on their clinical level of severity, will be classified as critically-ill. This clinical deviation from normal health will render the patient dependent upon a medical team that considers their practice, education, and associated research a specialty area with definite standards. These standards are derived from the patient's physical and psychosocial needs that result from his/her medical insult. Since the clinical conditions that may present are varied, the educational preparation of the staff combines a number of disciplines. There is no national training/curriculum model to use as a guide for flight nurse preparation, thus the Hartford Hospital Flight Nurse Educational Program (HHFNEP) was defined and implemented. An extensive selection process included physiologic and psychologic testing. This included the following criteria: 1) height and weight in proportion to body habitus; 2) musculoskeletal strength/ability to lift 75-100 lbs.; 3) no previous history of lumbosacral or other spinal trauma or surgery; 4) lumbosacral spine x-rays; 5) visual acuity 20-20 or correctible to same with lenses; 6) hearing acuity 15-15 or no more than 10 decibel loss in either ear; 7) pulmonary function testing (smokers were disqualified); 8) aerobic fitness, capable of completing Stage IV Bruce protocol treadmill stress test; 9) motion sickness resistance; 10) personality stability.

All applicants were given a clinical psychology interview and a Rorschach projection test prior to acceptance into the training program. The nine candidates began the full-time (5 day/week) HHFNEP on February 19, 1985. Seven weeks of didactic training were integrated with seven weeks of clinical rotations.

The eighteen-module program includes: 1) Emergency Medical Services; 2) Thoracic and Pulmonary Conditions; 3) Cardiovascular Conditions; 4) Electrocardiography and Dysrhythmia Recognition; 5) Abdominal and Pelvic Conditions; 6) Central Nervous System and Axial Skeleton; 7) Appendicular Skeleton; 8) Metabolic and Endocrine Conditions; 9) Obstetrics/Gynecology; 10) Drug Overdose and Poisonings; 11) Neonatology; 12) Pediatrics; 13) Environmental Conditions; 14) Soft Tissue/Maxillofacial/Eye/Ear; 15) Burns; 16) Sequelae to Trauma; 16) Behavioral Conditions; 17) Transportation/Operations/Safety. All modules provided the nurses with a strong foundation in physiology and the alterations in that physiology produced by illness or disease. To perfect their skills, the nurses spent a minimum of forty (40) hours in each of the following clinical areas: 1) Surgical Intensive Care Unit; 2) Pediatric Intensive Care Unit; 3) Coronary Care Unit; 4) Neonatal Intensive Care Unit; 5) Emergency Department; 6) Operating Room; 7) Advanced Life Support Ground Ambulance Service.

Additional experience was gained in the delivery room, with the intravenous therapy team, inhalation therapy, and in the autopsy and animal laboratories. In addition to the formal 532 scheduled hours, each flight nurse acquired additional hours becoming familiar with the helicopter, its equipment, and safety procedures.

Along with the necessary cognitive skills and knowledge the flight nurses were trained in the following manipulative skills: 1) endotracheal and nasotracheal intubation; 2) cricothyroidotomy; 3) needle-chest decompression and chest tube insertion; 4) venipuncture and venous cannulation (central and peripheral); 5) MAST use; 6) intravenous medication administration; 7) dysrhythmia recognition; 8) defibrillation and synchronized cardioversion; 9) nasogastric intubation; 10) splinting of extremities and spinal immobilization; 11) insertion of Gardner-Wells tongs for spinal traction; 12) monitoring and operation of intraaortic balloon pump, pacemakers, and other monitor devices; 13) neonatal transport and monitoring.

The completion of the flight nurse training program coincided with the arrival of the helicopter. Graduates completed an extensive post course testing process including written, practical, and oral examinations.

The flight nurses were also involved in learning the methods and techniques for optimum communication with community groups, allied health professionals, and all interested persons in order to familiarize the medical, professional, and lay public with the operational benefits and misuses of the helicopter program. The role of the flight nurse extends beyond her clinical interaction with patients and includes many other responsibilities spanning public education, research, and process evaluation.

Communications

The backbone of a critical-care transport system is the ability to communicate with many different services at all times. In order to discourage inappropriate use of the system only authorized personnel may summon the helicopter. They include EMTs, law enforcement agents, public safety personnel, and physicians. To access the program the toll-free telephone is **1-800-437-4378.** Secondly, prehospital personnel can also communicate on present EMS radio frequencies that connect to the Emergency Department of the Hartford Hospital.

There are different and discrete radio frequencies for the pilot of the helicopter to communicate with air traffic controllers so as to be aware of all air traffic in the vicinity of the mission. An intercom system in the helicopter permits the medical crew to talk with each other and with the pilot. When it is necessary to speak directly to the hospital or to ground personnel from the helicopter, radio communication through a central medical emergency direction/dispatch (CMED) center is initiated. The medical director of the program can communicate by cellular radio/telephone with the helicopter crew and the hospital at all times from any location. This extensive communication system will be monitored continuously by specially trained communicators at the Hartford Hospital. As well as coordinating these multiple communications, the dispatchers must track the flight path; this is achieved by continuous pilot to base communications and subsequent coordinate mapping by the dispatcher.

Equipment

The helicopter is built by Messerchmitt-Bolkow-Blohm (MBB) and is a BK-117 on contract with Rocky Mountain Helicopter Corporation. At any given time of the day, the helicopter will be ready for liftoff within five minutes. It will respond to a variety of clinical scenarios and therefore is equipped appropriately. Weight, compactness, and portability are essential concerns when procuring equipment for aeromedical use. Equipment for airway management, cervical spine immobilization, cardioresuscitative drugs, intravenous therapy, MAST use, and cardiac monitoring are available. Oxygen, suction, monitors/defibrillators, respirators are also on board. A neonatal incubator/isolette with monitors has been built onto a stretcher and is available as a module that can be placed on board in the event of a neonatal transfer.

Specialized equipment also includes a portable intraaortic balloon pump console that is compatible with in-hospital equipment.

Staffing Pattern

The BK-117 is a twin-engined aircraft capable of transporting four medical personnel and two patients. For this reason the program has the luxury of having a number of specialty personnel designated for flights. The flight nurse is responsible for receiving the report from either pre-hospital or hospital personnel depending on whether it is a scene or hospital to hospital transport. She is responsible for performing the necessary therapeutic and assessment interventions prior to boarding the patient on the aircraft.

She is also responsible for the overall management of the patient in flight. The permanent staff assigned to flight duty are the one flight nurse, the pilot, and one additional medical person. The second person will either be another flight nurse, a physician, or respiratory therapist depending on the patient's condition. The physicians involved in this program have also had additional training and extensive experience in trauma and critical care management. Each member of the team has carefully predetermined activities which they will perform during the mission. The flight nurse is responsible for communication to the hospital in order that information is appropriately transmitted to the receiving facility.

Summary

The final phase of development of a third generation aeromedical transport system is to reduce the cost to the individual user with emphasis on prevention in order to have the program remain medically sound. Identifying the determinants of disease/injury process is a time-tested, fundamental public health principle applied since the time Snow discovered the water pump as the cause of the spread of cholera in London in 1849. Water and waste treatment aided in the control of epidemics such as those caused by infectious diseases. Vaccinations control polio, smallpox, and rubella. Antiseptic techniques aid in the control of surgical sepsis. All of these processes have in common the principle of identifying the epidemiological determinants and distribution of disease and the incorporation of primary and secondary levels of prevention.

Research is on-going in the trauma field to isolate the determinants and strategies for control of the problem prior to the “event” phase. Auto-crashworthiness, deterrent laws, self-protection laws, and educational/persuasion strategies are on-going. The insurance industry bears much of the financial burden of the trauma problem and has a considerable interest in decreasing the $62 billion annual expenditure for trauma “post-event” reasons. If evidence can be generated, verified, and reproduced to support the claim that aeromedical systems decrease mortality, morbidity, and expense, then there may be interest to support such services across a wide population base. Such a system can be achieved by a voluntary insurance rider on automobile, health, catastrophy, or industrial insurance or governmental levy on alcohol, firearms, or motor vehicle usage. The precedent for this already exists in Switzerland where a voluntary 800,000 subscriber service underwrites the capital and operational costs of Swiss Air Rescue which provides medical transport world-wide.[34]

The first critical care helicopter service for the State of Connecticut and surrounding territories will provide a service to the people that has been tested and shown to reduce mortality both in Europe and in the United States. It involves the rapid transfer of critically-ill patients with highly- skilled flight nurses delivering potentially life-saving care. Transfers can be either scene to hospital or interhospital in nature. In addition, the helicopter, under special circumstances, can be used for disaster responses and organ transfer. Flights are expected to transfer trauma, burn, spinal cord injured, cardiac, and neonatal patients. The helicopter is equipped with specialized clinical and communicative devices. Constant internal medical and nursing audit and research is planned to monitor and adjust the system as needed. In addition, a task force has been assigned to oversee flight operations.

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Bilateral Postpartum Femoral Neuropathy

JAMES O. DONALDSON, M.D., DIANE WIRZ, M.D. AND JAN MASHMAN, M.D.

ABSTRACT–Femoral neuropathy following vaginal delivery is now rare although around 1900 over 3.2% of 2,480 deliveries in three series were so complicated. One quarter of these cases were bilateral as is the case reported. Cephalo-pelvic disproportion, dystocia and primiparity are common. Presumably these neuropathies are caused by the fetal head exerting continuous pressure upon the lumbar plexus and the intrapelvic femoral nerve, in bilateral cases, with the brow on one side and the occiput on the other. Women with neuropractic lesions and complete recovery may risk a trial of labor during a subsequent pregnancy with a smaller infant. Women whose axons were crushed with resultant incomplete recovery thereafter should be delivered by cesarean section.

Femoral neuropathy can be caused by intrapelvic conditions including hematomas, infiltrating tumors, appendiceal abscesses and trauma although ischemic diabetic neuropathy (neuralgic amyotrophy) is the most common cause in this era. [1] Compression of the femoral nerve is a complication of pelvic surgery, often caused by malpositioned self-retaining retractors. [2, 3] Femoral neuropathy following vaginal delivery is now a rarity [4, 5] although 80 years ago that category accounted for 62% of 136 reported cases of femoral neuropathy, whereas diabetes caused only 7%. [6, 7] Fully 3.2% of 2,480 deliveries by Ernst (1900), [8] Meyer (1901), [9] and Hauch (1906) [10] were complicated by postpartum femoral (anterior crural) neuropathy. One quarter of those cases were bilateral, as have been isolated cases reported subsequently, [4, 5, 11] including the case described hereafter.

Case Report

A 27-year-old primigravida vaginally delivered a healthy 2560g infant with a head circumference of 34 cm after laboring hard for 3 hours in Stage II. The caput presented; the position was not recorded. There was no clinical evidence for cephalo-pelvic disproposition. Pelvimetry was not done. She did not experience sudden severe leg pain during labor. Before pregnancy the patient was a well-conditioned cyclist who carried 50 kg on her 1.6 m frame.

After delivery the patient could not lift her left leg from her bed and could not walk on level surfaces unless she locked her knees in full extension. Paresthesiae were experienced over her anterior and inner thighs. The left iliopsoas muscles, both quadriceps femoris muscles and the left sartorius muscles were weak. Both knee jerks were absent. Pin pricks were blunted on the anterior thighs from inguinal ligaments to knees and in the "saphenous strip" extending middle of her inner thighs distally almost to her medial malleoli. Her cerebrospinal fluid and a myelogram, done because there had been an unsuccessful attempt to introduce a local anesthetic into her epidural space, were normal.

Her strength returned gradually over 6 months although she experienced dysesthesias in the distribution of the left saphenous nerve for an additional 6 months. Two years later, in the third trimester of her second pregnancy, her neurologic examination was normal. That childbirth was terminated by cesarean section because the fetal head of a larger child weighing 3300g did not engage. Postpartum leg weakness did not recur.

Discussion

The femoral nerve, the largest branch of the lumbar plexus, forms from the primary rami of L_2, L_3, and L_4 before penetrating and descending through the pelvis within the greater psoas muscle (Figure 1). After exiting the greater psoas muscle at the lower part of its lateral margin, the femoral nerve lies in a groove between that muscle and the iliacus, passing under the inguinal ligament before branching to innervate the quadriceps femoris, and sartorius muscles. Cutaneous branches supply superficial sensation to the anterior thigh and a medial strip extending from the ankle almost to the groin. An important anatomic and semantic point is that the femoral nerve does not innervate the iliopsoas muscle, which is supplied within the pelvis by a separate branch of the plexus formed from the L, and L, roots. Thus, although weakness of the iliopsoas muscle is sometimes included

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JAMES O. DONALDSON, M.D., Associate Professor of Neurology and Internal Medicine; Acting Chairman, Department of Neurology, University of Connecticut School of Medicine, Farmington, CT. DIANE WIRZ, M.D., Chief Resident in Neurology, University of Connecticut School of Medicine. JAN MASHMAN, M.D., Attending Neurologist, Danbury Hospital, Danbury, CT.

Reprint requests to: Department of Neurology, University of Connecticut Health Center, 263 Farmington Ave., Farmington, CT 06032 (Dr. Donaldson).

as a clinical characteristic of femoral neuropathy, it implies a proximal lesion of lumbar nerve roots or lumbar plexus and not a more peripheral lesion of the femoral nerve under Poupart's ligament or in the thigh.

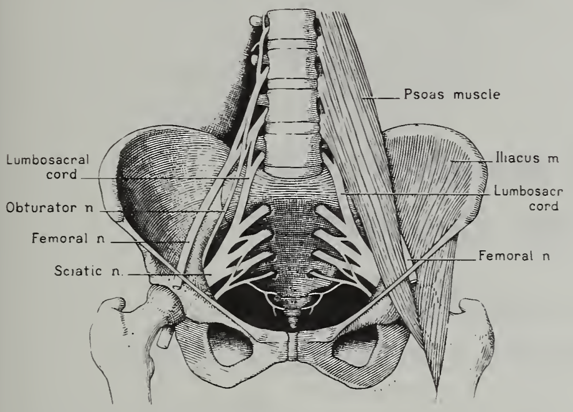

Figure 1

The relationship of the femoral nerve and the lumbosacral cord to the pelvis and psoas major muscle. From Cole JT: "Maternal obstetric paralysis," Am J Obstet Gynecol 52:374, 1946.

A Woman with postpartum "femoral" neuropathy usually, once allowed out of bed, finds herself unable to climb stairs although able to walk on level surfaces. She may recall a stab of pain into her knee, thigh or ankle during labor. The degree of motor and sensory involvement is variable. The patellar reflex is depressed, if not absent. Coexistent involvement of the obturator nerve will weaken the adductor magnus muscle. A zone of anesthesia to pin pricks within a larger area in which perception of light touch is diminished is characteristic of peripheral nerve lesions and will direct the diagnostician away from a lesion of the spinal cord or cauda equina, which must be considered especially if the problem is bilateral.

Paralysis of the femoral nerve has been attributed to strong flexion of the thighs on the abdomen with abduction and outward rotation of the hips which presumably compresses the femoral nerve against the inguinal ligament. [3, 12, 13] This mechanism may occur but in almost all postpartum cases iliopsoas muscle weakness bespeaks of a more proximal lesion within the pelvis. This is little reason to doubt that direct injury of the nerve trunks within the pelvis by either the fetal head or instruments is the cause of most cases of postpartum femoral neuropathy.

Cephalo-pelvic disproportion, dystocia, and primiparity are common features of deliveries resulting in postpartum footdrop and postpartum "femoral" neuropathy. In the former the lumbar trunk, constituted from L_4 and L_5 roots, is compressed against the sacral ala by the fetal brow. [14, 15] Postpartum foot drop is characteristically unilateral, occurring on the side opposite the presentation of the vertex (right occiput anterior = left brow posterior). [15] In contrast, a relatively large proportion of women with postpartum femoral neuropathy, 25% of 44 adequately detailed cases in the older literature, had bilateral weakness although the degree of weakness could differ. [7] Cases of unilateral postpartum femoral neuropathy are almost equally distributed between right and left sides. [12] Bilateral postpartum obturator neuropathies have also been reported. [12] Presumably these neuropathies are caused by the fetal head exerting continuous pressure bilaterally, with the brow on one side and the occiput on the other.

In most instances the prognosis is excellent because the injury was neuropractic. Thus, once the Schwann cells have repaired distorted myelin sheathes, full function is restored because the axons remained intact. Definite improvement is to be expected with 2 to 8 weeks and full recovery certainly with 6 months. If axons were crushed and Wallerian degeneration ensured, recovery is slow and often incomplete because regenerating axons must sprout long distances and may form neuromas.

Prevention of intrapelvic entrapment neuropathies during subsequent pregnancies requires recognition of any underlying cephalopelvic disproportion and an assessment of the severity of the first neuropathy. Cepalo-pelvic disproportion may predispose patients to recurrent nerve injury, as with one woman with 4 episodes. [12] The risk of permanent weakness with recurrent maternal obstetric palsies is unknown but the following recommendations are reasonable. Women who had axonal degeneration probably thereafter should be delivered by cesarean section. Women with neuropraxis, who recovered promptly and fully, may have a trial of labor if the fetus is smaller but should expect termination of childbirth by cesarean section should dystocia develop.

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Continuous Passive Motion (C.P.M.) Following Total Knee Replacement

ROBERT L. FISHER, M.D., KAREN KLOTER, R.P.T.,

BARBARA BZDYRA, R.P.T. AND JUDITH A. COOPER, R.P.T., M.A.

ABSTRACT—This retrospective study of 50 patients treated by conventional physical therapy and 50 patients having continuous passive motion (C.P.M.) following total knee arthroplasty demonstrated a beneficial effect from C.P.M. The total and post-operative length of hospitalization and number of physical therapy treatments to achieve rehabilitation goals were significantly reduced in the C.P.M. patients. No complications were encountered by the use of C.P.M.

Experimental studies[1, 2, 3] have indicated a beneficial effect of continuous passive motion (C.P.M.) on healing of articular and periarticular tissues. Clinically, C.P.M. has been applied particularly to post-operative management of total knee arthroplasty patients. Coutts et al,[4] in a multi-institutional study, found a more rapid gain in knee motion and shorter hospital stay in 137 patients having C.P.M. throughout their hospitalization when compared to 129 patients having conventional therapy. Davis[5] also found that C.P.M. facilitated the short-term rehabilitation after total knee arthroplasty. Young and Kroll,[6] however, found little difference in recovery of patients employing C.P.M. or conventional therapy. The present study was undertaken to review the Hartford Hospital experience with C.P.M. and to determine if it is useful in rehabilitation after total knee replacement.

Material and Methods

Fifty consecutive total knee patients treated with four days of post-operative splinting followed by conventional active assisted range of motion and muscle strengthening exercises were identified December 1982 through June 1983. The first fifty patients utilizing C.P.M. after its introduction at the hospital, July 1983 through February 1984, were also studied. All patients had identical pre-operative preparation and operating room routines. The procedures were carried out by eleven different surgeons but the relative input by surgeon was comparable for patients having C.P.M. and conventional therapy. Insall-Burstein and kinematic prosthetic designs were utilized in almost all patients and in approximately equal numbers in each patient group. The patient characteristics of the two groups are shown in Table 1. Except for an unexplained difference in age ($p < .02$), there was no statistical difference between the parameters for patients having C.P.M. and those having conventional physical therapy.

Table 1
PATIENT CHARACTERISTICS

	Group I *Conventional P.T.*	*Group II* *C.P.M.*
Mean Age	70.4 years	66.6 years
Sex	34 ♀, 16 ♂	32 ♀, 18 ♂
Osteoarthritis	46	47
Rheumatoid Arthritis	4	3
Knee range of motion pre-op	112.6°	113.0°

ROBERT L. FISHER, M.D., Director, Department of Orthopedics, Hartford Hospital; Clinical Associate Professor, University of Connecticut School of Medicine, Farmington, CT. KAREN KLOTER, R.P.T., Physical Therapist, Department of Rehabilitation, Hartford Hospital. BARBARA BZDYRA, R.P.T., Physical Therapist, Department of Rehabilitation, Hartford Hospital. JUDITH A. COOPER, R.P.T., M.A., Director, Department of Rehabilitation, Hartford Hospital, Hartford, CT.

Table 2
POST-OPERATIVE PHYSICAL THERAPY PROTOCOL

	Group I *Conventional P.T.*		*Group II* *C.P.M.*
Post Op. Days 1, 2, 3	Quadriceps setting Ankle motion exercises Pivot transfer on unaffected leg Out of bed in wheelchair	Post Op. Day 1	Quadriceps setting Ankle motion exercises Pivot transfers on unaffected leg Out of bed in wheelchair
Post Op. Day 4—Discharge	Twice daily P.T. sessions Progressive ambulation with appropriate assistive devices—walker to crutches to cane Knee range of motion exercises Strengthening exercises—short arc quadriceps, straight leg raising, massage and patellar mobilization Instruction in home exercise program	Post Op. Day 2—Discharge	Same as conventional P.T. Day 4—Discharge C.P.M. machine adjusted to 5-10° of range of motion gains after P.T. sessions C.P.M. machine discontinued when 90° of flexion achieved

The post-operative discharge goals for all patients were 90° of knee flexion, ability to straight leg raise and independent ambulation with appropriate support such as cane or crutches. The physical therapy protocols for the two groups are seen in Table 2. Patients in the conventional P.T. group had 30 minute P.T. sessions daily after splint removal on the fourth post-operative day. Patients utilizing C.P.M. were placed in the device* (Figure 1) in the recovery room. The range of motion was gradually increased from 30° to 90°. A 45 second to 1 minute cycle was utilized. When 90° of flexion was achieved in physical therapy session, the device was discontinued. The mean number of days in the C.P.M. device following surgery was 5.4.

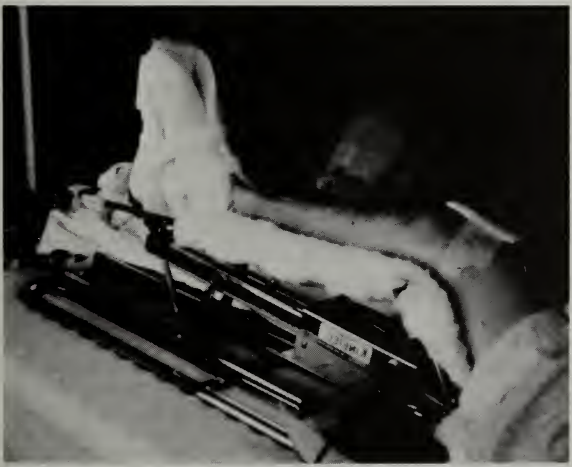

Figure 1
Continuous Passive Motion device in use.

Results

Achievement of Therapy Goals: There was a highly significant decrease in total length of hospitalization ($p = 0.0001$) in the C.P.M. group (median 12 days) when compared to the conventional group (median 17 days) (Figure 2). Furthermore, the post-operative hospitalization in the C.P.M. group (median 10 days) significantly differed ($p = 0.0001$) from the conventional P.T. patients (median 15 days) as seen in Figure 3. The number of days to achieve 80° and 90° of knee flexion were also significantly reduced by an average of two days in the C.P.M. patients ($p = 0.0001$). The rehabilitation goals were achieved with a significantly smaller number of physical therapy sessions ($p = 0.0001$) in the C.P.M. patients. The functional levels and use of assistive devices at discharge were identical for both groups.

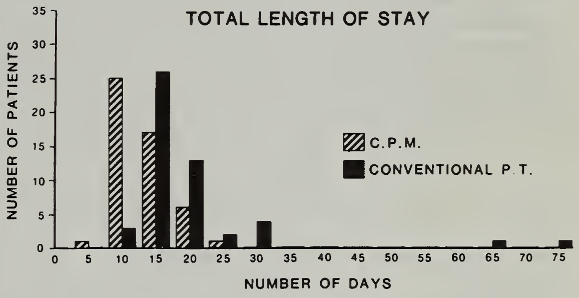

Figure 2
Total Length of Hospitalization

Pain: The C.P.M. machines were generally well tolerated though many patients complained of discomfort and confinement. There was a greater requirement for morphine ($p = .02$) by the C.P.M. patients during the immediate post-operative period. There was little difference in requirement of tylox and demerol but a significantly lower requirement for tylenol with codeine by the C.P.M. patients ($p = 0.05$).

Complications: The medical and surgical complications of the study patients are listed in Table 3. There did not appear to be any relationship between mode of post-operative rehabilitation and type of complication. Specifically, C.P.M. did not lead to any wound problems. There were no instances of clinical thrombophlebitis or pulmonary embolism. No patient in either group required manipulation under anesthesia to achieve motion. While the total number of transfusions was less for the C.P.M. patients ($p = 0.01$), the number of patients requiring transfusions did not differ between the two patient groups.

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*Richards Manufacturing Company

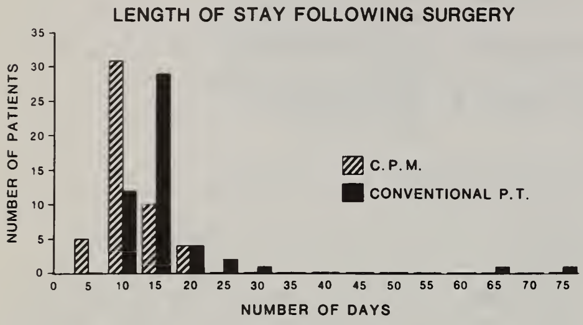

Figure 3
Post-Operative Hospitalization

Table 3

Complication		*Number of Patients*
Group I Conventional P.T.		
None		39
Fever		4
Wound swelling, drainage, ecchymosis		4
Miscellaneous		6
Urinary retention	– 1	
Respiratory arrest	– 1	
Myocardial infarction	– 1	
Transcient ischemic attack	– 1	
Dislocation of patella	– 1	
Inappropriate secretion of A.D.H.	– 1	
Group II (C.P.M.)		
None		32
Fever		9
Wound swelling, drainage, ecchymosis		5
Miscellaneous		6
Leg Pain	– 2	
Medial instability	– 1	
Hypotension	– 1	
Hematocrit 30 or below	– 2	

Hospitalization Costs: Owing to the shortened stay and lessened requirement for services, the C.P.M. patient hospital charges were estimated to be less than those for patients having conventional physical therapy. Definitive data regarding hospitalization costs were not available.

Discussion

In agreement with Coutts et al,[4] we found that C.P.M. had a beneficial effect on post-operative rehabilitation of total knee patients. This was particularly observed in the reduction of total and post-operative hospitalization time to achieve rehabilitation goals despite fewer physical therapy sessions. Our results in this regard were even better than those of Coutts el al[4] while using the C.P.M. equipment only about 5 days post-operatively. These findings have significant implications in view of the current D.R.G. medicare reimbursement of hospitals resulting from recent Federal legislation. The improvement in bed utilization and cost savings appeared to justify the modest investment in C.P.M. equipment.

It has been postulated that C.P.M. may inhibit pain through the "gate theory"[7] by which afferent pain impulses are blocked by proprioceptive input. Our data did not support this suppression of pain by C.P.M. except for a smaller requirement for C.P.M. patients for tylenol with codeine. In the early post-operative period, C.P.M. patients did in fact require more pain medication than those who were splinted. On the other hand, the C.P.M. devices were generally well tolerated and did not appear to cause any harmful effects.

Lynch et al[8] suggested that C.P.M. may reduce the incidence of thrombophlebitis in post-operative total knee patients on the basis of venograms. We did not observe any clinical thrombophlebitis in C.P.M. or conventional P.T. patients in this study.

Summary and Conclusions

This retrospective study of 50 patients treated by conventional physical therapy and 50 patients having continuous passive motion following total knee arthroplasty demonstrated a beneficial effect from C.P.M. The total and post-operative length of hospitalization and number of physical therapy treatments to achieve rehabilitation goals were significantly reduced in the C.P.M. patients. No complications were encountered by the use of C.P.M.

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Why Adolescent Medicine?—More Illustrative Cases

VICTOR C. STRASBURGER, M.D.

ABSTRACT—Adolescent patients can present many difficult diagnostic challenges. Physicians used to seeing children or adults may overlook important differences in history-taking, physical examination, and laboratory evaluation of adolescents. Five cases are presented in which fundamental principles of adolescent health care were ignored, and significant errors resulted. Physicians who treat teenagers should become specifically acquainted with adolescent physiology and psychology and not rely on their adolescent patients fitting into a "child" or an "adult" medical mode.

Although 66 percent of recent pediatric graduates rated their training in adolescent medicine as insufficient in the 1978 Task Force on Pediatric Education report,[1] some pediatricians, internists, and family practitioners continue to rely on adolescent illnesses mimicking childhood or adult illnesses sufficiently for a diagnosis to be made. Mistakes inevitably occur when teenagers are thought of medically as either large children or small adults. An earlier report described four such cases.[2] Five additional cases are now reported to illustrate the kinds of diagnostic misadventures that can occur when important principles of adolescent growth, development, and physiology are overlooked and how such errors can be avoided.

Case Reports

Case 1: Abdominal Pain and Vomiting

A 17-year-old white male was admitted by his physician for six days of episodic mid-epigastric abdominal pain, nausea, vomiting, and decreased appetite. During a six day hospitalization, tests obtained included three complete blood counts (CBC) and sets of electrolytes, an erythrocyte sedimentation rate (ESR), liver function tests (LFT's), multiple other chemistries, a chest x-ray (CXR), an abdominal flat-plate (KUB), and upper gastrointestinal series (UGI), and a barium enema (BAE). All were normal. One day before his discharge from the hospital, the patient readily admitted to another physician that he was a multiple-drug abuser—including Valium, Placidyl, Quaaludes, and marijuana—and that he had used 190-proof grain alcohol repeatedly in the past week. This information was not obtained on admission because the youth's physician had asked him about drug usage with his parents present in the examining room!

COMMENT: Confidentiality is absolutely essential in treating adolescents.[3] Sexual activity, suicidal thoughts or—as in this case—drug usage may go undetected if confidentiality is not discussed with both the parents and the teenager before the health visit begins. Often, anxious parents can be mollified by being included in the initial history-taking part of the exam; but they should then be asked to leave when the physical exam is done. The physician can then elicit the sensitive historical data at this time. Ideally, parents of children nearing age of 12 should be sent a letter by their physician explaining how the upcoming adolescent health visits will differ from previous ones (e.g., confidentiality, birth control, etc.).

Table 1

ADOLESCENT HISTORY: IMPORTANT DATA

1. Family:	intact? relationship with sibs conflicts with parents
2. School:	grade level course grades discipline problems career goals
3. Social:	friends dating behavior drugs: cigarettes, alcohol, marijuana, cocaine, stimulants, depressants, hallucinogens sex: heterosexual or homosexual activity sexual intercourse contraception previous venereal disease

Case 2: Prolonged Vomiting

A 17-year-old white female was admitted by her physician for vomiting and abdominal pain of two weeks' duration. Vomiting occurred twice each day but was not accompanied by diarrhea or fever. Physical exam

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VICTOR C. STRASBURGER, M.D., Associate Clinical Professor of Pediatrics, Yale University School of Medicine; Assistant Clinical Professor of Pediatrics, University of Connecticut School of Medicine.

Reprint requests to: 407 Hammertown Rd., Monroe, CT 06468 (Dr. Strasburger).

was said to be normal. The purpose of the admission was to observe her and obtain an UGI. While doing the admission history and physical, a pediatric resident obtained the additional information that the patient's last menstrual period (LMP) had been six weeks ago and she was sexually active without using any contraception. A pelvic examination revealed a hyperemic cervix, a 6-8 week size uterus, and a 2-minute urinary HCG test was positive. The patient was discharged from the hospital after appropriate pregnancy counselling.

COMMENT: If current pregnancy rates continue, an average of four in ten teenage girls will become pregnant by the time they have completed their adolescence.[4] A complete menstrual history, including sexual activity, must be obtained for any medical evaluation to be complete. In addition, pediatricians must acquaint themselves with adolescent gynecology if they are to successfully see adolescent female patients.[5] Although one study documents increased physician accuracy during the past fifteen years in making the diagnosis of pregnancy in adolescents,[6] delays can still result in increased morbidity and possible mortality. Confusion between sexually-acquired diseases and non-sexually acquired diseases (e.g., appendicitis vs. pelvic inflammatory disease or juvenile rheumatoid arthritis vs. gonoccocal arthritis) can also be avoided when a sexual history is obtained.

Table 2
TYPES OF PREGNANCY TESTS

I. Urine (slide)
  *Sensitivity: 500-2000 m.IU HCG
  *Time required: 2 minutes
  *Positive: day 30-40 of menstrual cycle
II. Urine (tube)
  *Sensitivity: 200-1000 m.IU HCG
  *Time required: 1-2 hours
  *Positive: day 24-40 of menstrual cycle
III. Serum, qualitative: (Biocept G, Wampole)
  *Sensitivity: 200 m.IU HCG
  *Time required: 1 hour
  *Earliest Positive: day 24 of menstrual cycle
IV. Serum, quantitative: b-HCG
  *Sensitivity: 6-50 m.IU HCG
  *Time required: 1 hour
  *Earliest Positive: day 20-24 of menstrual cycle

Adapted from: Neinstein LS. Adolescent health care—a practical guide. Baltimore: Urban & Schwarzenberg, 1984.

Case 3: Heavy Menstrual Periods

An 18-year-old white female was admitted by her gynecologist because of heavy and irregular menstrual periods for the past year. They occurred biweekly, lasted several days, and were heavy in flow but without clots. She was not sexually active. Symptoms also included weakness, dyspnea, and syncope. On physical exam, her vital signs were normal, BP 120/80 without an orthostatic change, and her pelvic exam was normal. An hematocrit was 24.3 with a hemoglobin of 8.0 gms. Platelet count was 377,000/pl. She was transfused with two units of packed red blood cells and a dilitation and curettage (D&C) was performed, which showed a menstrual endometrium.

COMMENT: Dysfunctional uterine bleeding (DUB) is a common disorder among adolescent females—it affects 10 to 15 percent of all gynecologic patients and over 20 percent of cases begin during adolescence.[7] The assessment of the adolescent with DUB is straight-forward (see Table 3), although the treatment regimen may vary. Nevertheless, a D&C —either for diagnostic or therapeutic purposes—is almost never indicated, and transfusions should be used conservatively.[8] Whereas an adult woman will ordinarily undergo a D&C to rule out endometrial pathology, this is not a consideration in adolescent females and is usually unnecessary.

Table 3
EVALUATION OF ADOLESCENTS WITH DYSFUNCTIONAL UTERINE BLEEDING

1. History and physical exam
2. Pelvic exam
3. Laboratory: CBC with differential
  Platelet count
  Clotting studies (if warranted by hx or severity)
  Thyroid studies (if warranted by hx or physical exam)
  Culture for gonorrhea (if sexually active)
  Pregnancy test (if sexually active)
4. Consider: Hospitalization if hemoglobin < 10 gms. or ectopic pregnancy suspected
  Gynecology consult
  Ultrasound
  Other hormonal studies as indicated

Cases 4 and 5: Adenopathy

A 16-year-old white male was admitted for biopsy of a large femoral mass of five days' duration. He was otherwise completely healthy and his past medical history unremarkable except for an allergy to cats—his family had two! On exam, he had a smooth, well-circumscribed, minimally tender group of femoral nodes, the largest measuring 2 x 3 cms. The pathological specimen contained multiple suppurative granulomas and follicular hyperplasia, most consistent with Cat Scratch Fever.

A 13-year-old white male was admitted for evaluation of large axillary nodes. Present for two weeks, they were rubbery, non-tender, and measured 1 x 1.5 cms. each. At an office visit, an enlarged spleen had been felt; and a liver-spleen scan showed moderate hepatosplenomegaly. The patient was otherwise well and denied fevers or anorexia. The family owned four cats. On admission to the hospital, no hepatosplenomegaly was felt. A CBC and CXR were normal. No other laboratory tests were done prior to a biopsy, which showed reactive lymphadenitis, suggestive of Toxoplasmosis.

COMMENT: Adenopathy in an adolescent can be alarming to both patient and physician, but an excisional biopsy is not always warranted. Both cases were done using general anesthesia; both required hospital stays of several days; and in both cases the diagnosis could have been established easily through an appropriate medical workup (see Table 4). Moreover, excisional biopsy in Cat Scratch disease is usually contra-indicated due to poor wound-healing at the site.[9] Physicians and families will be reassured by knowing that infectious mononucleosis is about 250 times more common in adolescents than lymphoma[2] and that many studies[10-12] have established useful criteria for deciding who needs to be biopsied.

Adolescents can make exciting and challenging patients. They have their own unique style and their own psychology and physiology. Failure to appreciate these will result in physicians either missing diagnoses, ordering too many tests that may be invasive as well as costly, or not attracting many adolescent patients at all. Many of the 40 million Americans between ages 10 and 21 (nearly 20% of the entire population) have serious medical and psychological problems, and it is the only age group in America where the mortality rate is increasing.[13]

Physicians should be sensitive to adolescents as a unique group of patients and re-acquaint themselves with the fundamental principles of adolescent medicine [14] rather than treating them in the more traditional mode as being large children or small adults.

Table 4

EVALUATION OF ADOLESCENTS WITH LYMPHADENOPATHY

1. History and physical exam:
    Hx: Sore throat, fever, URI sx
        Weight loss, arthritis
        Cats or cat scratches
        Local trauma
        Medications
    Physical exam: Does patient look ill or well?
        Vital signs, weight
        Periorbital edema
        Soft-palate petechiae
        Enlarged tonsils
        Liver or splenic enlargement
        Size, consistency, and location of enlarged nodes
        Local trauma or infections
2. Laboratory: CBC with differential
    ESR
    Tine test or PPD
    Monospot
    If needed: Titers for toxoplasmosis, cytomegalovirus (CMV), and Epstein-Barr virus
        Urine for CMV
        Hepatitis profile
        Liver function tests
        CXR
        Aspiration of node
3. Excisional biopsy only when necessary, with local anesthesia whenever possible.

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Cyclosporine

DAVID PLATT, PHARM.D. AND LAURA CECCORULLI, B.S., R.PH.

Introduction

The recent introduction of cyclosporine, (Sandimmune, Sandoz), represents a major advance in immunosuppressive therapy. As a potent immunosuppressive agent which lacks significant myelotoxic properties, cyclosporine (CsA) has become an important factor in the improving success of organ transplantation. [1-3] Cyclosporine (formerly cyclosporin A), a metabolite of the fungus *Tolypocladium inflatum* Gams, is a cyclic undecapeptide composed of 11 amino acids with a molecular weight of 1202. It is a neutral and lipophilic compound. [1]

Pharmacology and Pharmacokinetics

The precise mechanism of action of CsA is still unknown and has been recently reviewed. [2,3] Studies have shown that the administration of CsA results in the inhibition of antibody formation to T-cell dependent antigens allowing for the suppression of delayed-type hypersensitivity reactions. More specifically, CsA prevents the T-helper cells from producing T-cell growth factor (interleukin-2), and also prevents the precursor cytotoxic T-cell from acquiring a receptor for interleukin-2. This effect is reversible such that if CsA is either discontinued or the dose lowered, interleukin-2 formation could resume and result in possible graft rejection. [4-6]

The pharmacokinetics of CsA are complex and poorly understood. [3,7] The absorption of CsA from the gastrointestinal tract is slow, incomplete, and unpredic-

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DAVID PLATT, PHARM.D., Clinical Pharmacist in Surgery, Hartford Hospital, Hartford, CT; Assistant Clinical Professor, University of Connecticut School of Pharmacy, Storrs, CT; LAURA CECCORULLI, B.S., R.PH., Staff Pharmacist, Hartford Hospital.

table.[1,8] CsA undergoes first pass metabolism resulting in an oral bioavailability averaging 30%.[3] Several factors have been shown to alter CsA bioavailability. Malabsorption of oral CsA by liver transplant recipients, and by patients with diarrhea can decrease bioavailability.[9,10] Time-dependent improvement in CsA bioavailability has been observed in liver and renal transplant patients.[3] Factors such as influence of food or enterohepatic recirculation may account for this phenomena.[3,7] Peak blood concentrations are reached about 2 to 4 hours after the orally administered dose, however, time to peak concentration variation has been reported.[7] Because of CsA's lipophilic nature, it has a high tissue affinity with a relatively slow elimination from tissues, most notably the liver, renal fat, and the endocrine glands.[11] CsA is highly bound (>90%) to blood proteins, primarily high density and low density lipoproteins.[11,12] The clinical significance of this binding may be important in situations where lipoprotein profiles are altered such as renal impairment and liver dysfunction.[3]

CsA is extensively metabolized by the liver, producing at least 15 inactive metabolites.[1] The cytochrome P-450 system appears responsible for these metabolic pathways. Because hepatic dysfunction can decrease the elimination of CsA, dosage adjustments (guided by CsA blood levels), may be necessary.[13] The major route of CsA excretion is biliary, with only 6% of the dose excreted unchanged in the urine.[1,14] The average elimination half-life for adults is 19 hours (range 1-60 hours).[1,3,7] Cyclosporine is not removed by hemodialysis.[15]

Presently, individualization of CsA dosage is aided by monitoring CsA trough concentrations. However, several unresolved controversies exist regarding this practice.[3,7] The first disagreement is which CsA assay technique should be used for monitoring: radioimmune assay (RIA) or high pressure liquid chromatography (HPLC). Clinically, RIA is the most commonly used assay and is available commercially. However, this assay measures indiscriminately any cyclosporine-parent drug and metabolites. The HPLC technique can separately quantify parent and metabolite; however, this assay is not as clinically feasible as RIA.

The second controversy is whether CsA should be measured in serum/plasma or whole blood. Serum/plasma CsA concentrations are temperature dependent, whereas whole blood CsA concentrations are influenced by hematocrit. Standardized incubation (time, temperature) makes it feasible for most laboratories to monitor serum/plasma CsA.

The third controversy involves the relationship of CsA concentration to immunosuppression and toxicity. No therapeutic range has been firmly established.[3,7] The manufacturer recommends that trough whole blood concentrations (RIA) be maintained between 250 and 800 ng/ml, and that trough serum/plasma concentrations be maintained between 50 and 300 ng/ml.[16] More research is necessary to establish the clinical usefulness of monitoring CsA levels.

Indications

CsA is indicated for the prophylaxis of organ rejection in kidney, liver and heart allogenic transplants. CsA may also be used in the treatment of chronic rejection in patients previously treated with other immunosuppressive agents.[16]

CsA is currently being tested in other transplants including pancreatic and bone marrow transplantation.[1-3] Also, CsA has an antiparasitic effect not linked to immunosuppression. It has been studied in the treatment of malaria and schistosomiasis, and synergy with pyrimethamine has been reported.[17]

Clinical Trials

Numerous clinical trials have evaluated the effectiveness of CsA in suppressing graft rejection and improving patient survival following transplant procedures.[1-3] Randomized, controlled trials comparing CsA to standard immunosuppressive protocols (azathioprine, prednisone, ATG) in renal transplantation have been conducted.[18-24] Table 1 summarizes the results of these trials conducted in renal transplant patients. Recently, Merion et al[25] reported data from renal transplant patients who had been followed-up for 4½ years. Table 2 summarizes these data. Although these results are encouraging, statistical significance between CsA and standard regimens was reached only in studies where graft survival rates in the standard protocol groups were less than 70%. This implies that CsA may benefit specific subgroups of renal transplant recipients. These specific subgroups still need to be identified.

The use of CsA in liver transplantation has also been very positive. Before CsA use, the one-year graft survival rate ranged between 20-40%.[1] Starzl et al reported a one-year patient survival rate of 60-80% with use of CsA and low dose prednisone.[26] A decrease in postoperative infections has also been observed in these CsA treated patients. Improvement in survival in CsA treated patients has been observed in heart and heart lung transplantations as well.[1-3]

Adverse Effects

The most common adverse effect of CsA is nephrotoxicity, usually manifested by a slowly rising serum creatinine and decreasing creatinine clearance.[1-3] The nephrotoxicity is frequently non-oliguric with associated hyperkalemia, decreased bicarbonate, proteinuria, granular and hyaline casts, and impaired urinary concentrating abilities.[27,28] Perhaps the most bothersome problem about CsA use in renal transplant patients is the difficulty in distinguishing nephrotoxicity from rejection. The nephrotoxicity may be dose-dependent and, in some patients, avoided if trough serum CsA concentrations are kept below 200 ng/ml; however, low trough CsA con-

Table 1

CLINICAL TRIALS OF CsA IN RENAL TRANSPLANTATION (ADAPTED FROM REFERENCE [29])

Trial	*Type of Transplant*	*Protocols*	*No. of Patients*	*1-yr. patient survival, %*	*1-yr. graft survival, %*	Rejection, %
Australian	CAD	CsA	30	93	70	83
Multicenter [18]		A + P + ATG	30	97	80 NS	93
Canadian	CAD	CsA + P	103	97	80	159**
Multicenter [19]		A + P + ATG*	107	89	64 p = 0.003	157**
European	CAD	CsA	117	94	72	86
Multicenter [20]		A + P	115	92	52 p = 0.001	91
Birmingham [21]	CAD	CsA + P	35	94	77	63
		A + P	33	91	85 NS	64
Boston [22]	CAD	CsA + P	76	95	78	53
		A + P	36	93	53 p = 0.01	72
Denver/	CAD	CsA + P	38	99	90	–
Pittsburgh [23]		A + P	32	99	50 p = 0.02	–
Minneapolis [24]	CAD or	CsA + P	92	92	87	31
	LRD	A + P + ATG	90	95	80 NS	58

KEY: CAD = cadaver kidney; LRD = living-related-donor kidney; CsA = cyclosporine; A = azathioprine; P = prednisone; ATG = antithymocyteglobulin; NS = not significant

*only some of the control patients received ATG
**total episodes

Table 2

LONG-TERM FOLLOW-UP OF CsA IN RENAL TRANSPLANTATION

Trial	*Type of Transplant*	*Protocols*	*No. of Patients*	*4-yr. patient survival, %*	*4-yr. graft survival, %*	*Rejection, %*
Cambridge [25]	CAD	CsA	79	70	86	62
		A + P	29	62	76 NS	66

centrations do not exclude nephrotoxicity.[2] If CsA dosage reductions fail, the renal function will improve in many patients after conversion to azathioprine and prednisone.[29] Long term cyclosporine use has been reported to cause irreversible, progressive nephropathy.[30]

Other serious and bothersome adverse effects have been attributed to CsA use.[1-3] Hepatotoxicity, characterized by rising LFT's and bilirubin, appears to be dose-dependent and reversible with dosage reduction. Hypertension, especially in heart transplant patients, has been observed with CsA. Adverse neurologic effects include headache, mild transient tremor, mood changes, and seizures. Hypomagnesemia may account for many cases of CsA neurotoxicity.[31] Also, hirsutism, abdominal discomfort, and nausea/vomiting may be seen in CsA treated patients.

A common complication seen in transplant recipients is infection. Early data suggested that CsA treated patients had a lower incidence of post-transplant infection as compared to patients receiving azathioprine and prednisone; however, subsequent larger trials have not confirmed these data.[20,24,29] In particular, viral infections and Pneumocystis carinii pneumonia can occur in CsA treated patients.[29]

Drug Interactions

Several drug interactions have been reported with CsA.[3,7,32] Drugs known to affect the cytochrome P-450 hepatic enzymes can interfere with CsA metabolism. Phenytoin and phenobarbital have both been shown to decrease CsA concentrations. Induction of hepatic metabolism is believed to be the mechanism of this interaction. Trimethoprim-sulfamethoxazole has also been reported to cause a decrease in CsA concentrations. Cimetidine has been associated with elevated CsA concentrations. Increased risk for nephrotoxicity may be encountered with concurrent use of CsA and amphotericin B, aminoglycosides, and melphalan. The high alcoholic content of the CsA vehicle (12.5% by volume for the oral form, 32.9% by volume for the intravenous form) may produce clinically important drug-alcohol interactions with such drugs as metronidazole, disulfuram, and cephalosporins (cefamandole, moxalactam, cefoperazone), and CNS depressants.

Dosage and Administration

Many different CsA dosage protocols have been used in organ transplantation.[1,3,16]

The intravenous dose of CsA is ⅓ the oral dose. The manufacturer has suggested an initial dose of 5 to 6 mg/kg/day infused slowly over 2 to 6 hours to prevent nausea, flushing, and paresthesias.[3] The patient should be changed to oral therapy as soon as possible.

The manufacturer suggests that the initial oral dose of CsA be 15 mg/kg administered 4 to 12 hours prior to transplantation. The maintenance oral dose should be 15 mg/kg for 1 to 2 weeks with a slow gradual tapering of 5% to 5 to 10 mg/kg day. Dosage should be guided by monitoring serum CsA concentrations. The drug has a very unpleasant, oily taste. To make the oral solution of CsA more palatable, dilution in milk, chocolate milk, orange juice or apple juice at room temperature is strongly encouraged.

Cost

CsA is available as an intravenous injection in a 5 ml ampule (50 mg CsA/ml) and a 50 ml oral solution (100 mg CsA/ml). The daily pharmacy acquisition cost for a 60 kg patient receiving an initial 6 mg/kg/day dose is about $29. For the same patient receiving an oral maintenance dose of 10 mg/kg/day, the pharmacy acquisition cost for a 30-day supply of oral solution is about $500. This corresponds to an annual patient cost of about $7100.

Conclusion

CsA is a new immunosuppressant used in organ transplantation. Compared to conventional immunosuppressive therapy, CsA appears at least as effective in reducing graft rejection and patient mortality. Although less toxic than standard immunosuppressants, nephrotoxicity may limit its use. More patient data and experience, especially regarding long term use, is still needed to better define CsA's role in transplantation.

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Important Advances in Clinical Medicine

Epitomes of Progress—Emergency Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in emergency medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in emergency medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Emergency Medicine of the California Medical Association and the summaries were prepared under its direction.

Autotransfusion

Autotransfusion was first used in 1818 by Blundell for postpartum hemorrhage. The Vietnam War showed the need for immediate availability of compatible blood in many cases of major trauma. Cardiopulmonary bypass procedures have provided necessary clinical experience and experimental data. Now cases of civilian trauma are benefiting from the use of autotransfusion.

In an emergency department, autotransfusion offers immediately available blood at room temperature for an exsanguinating patient. Blood supplied by autotransfusion is fresh and compatible. Procoagulation factors VIII and IX, absent in bank blood, are at nearly 100% of normal activity. Platelet levels are low but significantly higher than in bank blood. Hypofibrinogenemia is a consistent finding; however, there is no evidence of coagulopathy until half a patient's blood volume has been retransfused. In transfusions of less than 4,000 ml, the liver can replenish the circulation with fibrinogen. Studies of systemic effects showed no difference in prothrombin, partial prothrombin time, plasma hemoglobin concentration, plasma fibrinogen concentration and fibrinogen-fibrin degradation products in autotransfusion recipients versus recipients of bank blood.

Erythrocyte hemolysis may occur with vacuum collection pressures of greater than 60 mm of mercury. This appears to be well tolerated. No cases of renal failure have been reported.

Sepsis from contaminated blood has been a major concern in autotransfusion. There seems to be minimal risk from isolated hemothorax. Even blood with enteric, biliary or urinary contamination seems to be safe with the administration of broad-spectrum antibiotics. Most authorities consider autotransfusion with contaminated blood advisable only in the most dire circumstances.

Microemboli with pulmonary and renal complications have occurred. This problem is alleviated with micropore filtration. Air embolism has been extremely rare with gravity-assisted reinfusion techniques.

The most common device in emergency departments is the Sorenson autotransfuser. There are many modifications of this basic type of system. It is inexpensive, rapidly assembled and easy to use. Systems incorporating cell washers and pumps are more appropriate in an operating room where a technician is available.

Paul M. Freitas, M.D.
Oakland, California

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Ciguatera Toxin Poisoning

Ciguatera (from *cigua,* the poisonous turban shell snails of the Spanish Antilles) toxin poisoning follows the ingestion of tropical and semitropical benthic marine fish. Most cases involve the barracuda (family Sphyraenidae), red snapper (genus *Lutjanus*), jack (family Carangidae), grouper (family Serranidae) and parrot fish (family Scaridae), which accumulate a series of at least five toxins that originate in the dinoflagellate *Gambierdiscus toxicus.* Larger animals in the food chain assume greater toxicity. The toxin is without taste and is impervious to gastric acid, freezing temperatures and extreme heat.

The toxin, which appears to be composed of lipid-soluble and water-soluble components, possesses cholinomimetic and anticholinesterase activity. Major toxic effects have been linked to sustained depolarization of nerve and muscle membranes, caused by a putative blockade of calcium sites that regulate the passive sodium pores.

Symptoms of ciguatera toxin poisoning are noted from 15 to 30 minutes after ingestion, with rare delay of as long as 24 hours. Gastroenteritis is followed by pruritus, paresthesias, the pathognomonic reversal of hot and cold sensation, hypersalivation, odontalgia, dysphagia, malaise, myalgias, diffuse or focal weakness, muscle fasciculations, tremor, athetosis, meningismus, ataxia, blurred vision, seizures, bradycardia, hypotension, ascending paralysis, coma and respiratory failure. Fatalities are rare. Vomiting and diarrhea resolve in from 24 to 48 hours; dysesthesias and subtle neurologic abnormalities may persist for as long as two months.

Therapy is supportive. In managing a case of acute ingestion, the use of magnesium-based cathartics should be avoided, as they may augment a calcium channel blockade. Bradyarrhythmias are responsive to administration of atropine sulfate. An intravenous infusion of calcium gluconate for hypotension has been recommended, but this treatment is as yet empirical.

The lipid-soluble component can be extracted from fish flesh with serial solvent elutions. A radioimmunoassay can detect ciguatera toxin in fish flesh, but does not identify a human syndrome. Although counterimmunoelectrophoresis of toxic (human reaction or in vivo mouse bioassay) fish extracts and human serum confirms toxic fish specimens, specimens of both immune and nonimmune human serum show precipitin reactions with toxic extracts. Therefore, it is not yet possible to conclude that affected persons have ciguatera toxin-specific antibody. Until further tests are available, the diagnosis of ciguatera toxin poisoning must be made clinically.

Paul S. Auerbach, M.D.
San Mateo, California

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The Use of Hemoperfusion to Treat Poisoning and Drug Overdose

The goal in treating a case of poisoning is to limit the effects of the poison and thus prevent death or serious complications. The simplest way to prevent toxic effects is to interrupt absorption from the gastrointestinal tract with gastric-emptying procedures and adsorption with activated charcoal. Once the toxin has been absorbed into the body, its toxicity may be countered by intensive supportive care including airway protection, assisted ventilation and fluid management. These widely used treatments have reduced the mortality of poisoned patients requiring hospital care to less than 1%. More invasive and complex methods such as hemoperfusion, which increases the elimination of poisons from the system after absorption, have been widely used but poorly studied.

Hemoperfusion is done by passing a victim's blood directly over an adsorbent material (charcoal or resin) and returning the filtered blood to the patient. Standard hemodialysis roller pumps and vascular catheters are used, and the patient must be receiving heparin. Flow rates of as high as 300 ml per minute can be achieved, and when there is good extraction by the adsorbent column, significant removal is possible for some toxins. However, for a drug or poison to be effectively eliminated from the body, it must be readily accessible for such blood "cleansing"—that is, it should not be highly tissue bound or otherwise sequestered outside of the bloodstream. Thus, drugs with very large volumes of distribution, such as digoxin, tricyclic antidepressants, phenothiazines and narcotics, are unlikely to be significantly removed, whereas those with small volumes of distribution, such as theophylline, phenobarbital, salicylate and acetaminophen, are readily available for elimination.

Before undertaking hemoperfusion, one must decide whether the benefits of accelerated toxin removal outweigh the risks of vascular access and anticoagulation. For most cases of intoxication, simple supportive measures are satisfactory. Situations that might prompt the use of hemoperfusion include clinical deterioration despite maximal supportive measures; the presence of a known lethal dose or blood concentration, or the loss of normal excretory mechanisms, such as with renal or hepatic failure.

Hemoperfusion may be undertaken for phenobarbital overdose when hypotension and metabolic acidosis persist despite warming, fluids and pressors. It is indicated for theophylline intoxication when there are intractable seizures or when blood concentrations are very high (above 100 mg per liter, or 60 mg per liter in patients with chronic, accidental overmedication). It is currently recommended for cases of paraquat poisoning—even though the elimination rate is low—because of the lethality of untreated intoxication. Although hemoperfusion has been used for cases of tricyclic-antidepressant overdose, it has not been shown to remove significant amounts of the drug or its metabolites.

Although hemoperfusion is a useful method of removing some toxins, it has limited indications. Complications include vascular trauma from catheter placement, local hematomas, air embolism, intracranial bleeding and thrombocytopenia. Repeated-dose oral activated charcoal may eventually prove to be a preferable method of accelerated elimination in some patients, especially those with less severe poisoning or with contraindications to heparinization.

Kent R. Olson, M.D.
San Francisco

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The Computer as Physician? Automatic External Defibrillation

Recent evidence has suggested rather convincingly that early external defibrillation is the single most important factor in successfully reversing out-of-hospital cardiac arrest. However, many communities have neither the patient volume nor the financial resources to initiate and maintain full advanced life-support skills in their emergency medical services personnel. Basic emergency medical technicians can be trained to recognize and treat cases of ventricular fibrillation, and clinical studies have shown improvement in hospital discharge rates of around 15% for cardiac arrest victims so treated. Unfortunately, such training is not inexpensive and requires frequent refresher courses. A computerized, self-contained device (Heart Aid, Cardiac Resuscitator Corporation, Wilsonville, Oregon) that automatically identifies ventricular fibrillation and applies countershocks is now commercially available. This automatic defibrillator requires very little training to use and costs about as much as a standard monitor-defibrillator. Electrodes are applied to the tongue and epigastrium, the machine is activated and cardiopulmonary resuscitation interrupted for a maximum of 15 seconds. The device then analyzes the electrocardiographic findings and checks for spontaneous respirations (via a breath sensor in the mouth). Countershocks are delivered when appropriate and results analyzed. Prerecorded voice messages prompt emergency medical services personnel to assist respirations, check for pulses, continue cardiopulmonary resuscitation and so forth. Rozkovec and co-workers showed the safety and efficacy of the tongue-epigastric route for cardioversion, delivering charges of up to 320 J. Jaggarao and colleagues treated 11 consecutive patients in cardiac arrest with the automatic defibrillator: six were successfully defibrillated and resuscitated and five were discharged from hospital. The device also has an automatic external pacing function that has not been as extensively studied. Clinical trials are ongoing in many states, and results continue to support the addition of the automatic external defibrillator as a valuable tool for emergency medical services personnel.

Steven M. Joyce, M.D.
Tucson

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Aeromedical Emergency Care

Rotorcraft aeromedical emergency care was born during the closing days of World War II when the early Sikorsky helicopters were used to evacuate casualties in the European theater. The extensive use of rotorcraft for this purpose did not take place until the Korean conflict, during which time both the Army and Air Force used Bell 47s to evacuate casualties to Mobile Army Surgical Hospital (MASH) units. This expertise was extended to the civilian sector following the close of the Korean conflict in the form of dual-purpose public safety services in which rotorcraft was used for both public safety missions, such as law enforcement and fire suppression, and emergency medical service missions. Due to the dual service nature, the medical expertise of the flight crews was very limited. In the early 1970s, rotorcraft began to be based at hospitals and fully committed to emergency medical service missions. Because a rotorcraft was stationed at a hospital, the medical flight crews could be selected from the more experienced medical personnel within the institution. Flight nurses became the mainstay of these services and brought a level of medical expertise to the field heretofore unseen. At that time, paramedics could place peripheral intravenous lines, administer a limited number of drugs and use the defibrillator/cardioverter. Flight nurses, on the other hand, were trained to place endotracheal tubes, thoracostomy tubes, central intravenous lines, administer a wide spectrum of drugs and do all those procedures paramedics could do. In 1976 physicians were placed on hospital-based rotorcraft emergency care services and the potential for bringing even a higher level of expertise to the field became limited only by the training of a physician. The capability to do cricothyroidotomy, pericardiocentesis, place cranial trephines and even perform open toracotomies in the field became a reality.

Recently, the impact of these services on mortality from blunt trauma has been investigated in two studies. In the first, the mortality of 150 consecutive trauma patients treated at the site of injury and transported to a trauma center by standard land prehospital care services was compared with that of 150 consecutive trauma patients treated at the site of injury and transported to the same trauma center by a rotorcraft aeromedical service staffed by a physician and nurse. A statistical analysis designed to predict mortality based on injury severity showed that the mortality of the land group was statistically no different from that of a large index trauma patient population treated at a major trauma center. There was a 52% reduction in predicted mortality of the aeromedical group, which was statistically significant ($P<.001$).

In the second study the same methodology was used; the mortality of 1,273 patients treated and transported by seven different hospital-based rotorcraft aeromedical services was compared with that of more than 3,000 patients treated by land emergency medical services and transported to 45 trauma centers across the United States. This study showed a 21% reduction in the predicted mortality, which was also statistically significant ($P<.001$).

In both studies the patients treated by the aeromedical services were more seriously injured than those treated by the control services. In addition, of those patients who died, death was caused by more severe injuries in the aeromedical group; of those patients who survived, survival was despite more serious injuries in the aeromedical group. The major reduction in predicted mortality was in those aeromedical patients who had suffered more severe injuries, representing less than 20% of all trauma patients treated by these services.

In conclusion, it appears that hospital-based aeromedical emergency care services may reduce mortality of at least blunt trauma patients, and that the most seriously injured patients seem to receive the greatest benefit from these services.

William G. Baxt, M.D.
San Diego

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Calcium Channel Blockers in Emergency Medicine

Over the past few years a new class of drugs, the calcium channel blockers, has been introduced. As a group, these drugs inhibit the intracellular movement of extracellular calcium through voltage-dependent membrane channels. Because cardiac and vascular smooth muscle is particularly dependent on calcium for its function, it is not surprising that calcium channel blockers have specific value in the treatment of cardiovascular disease. The calcium channel blockers most recently released in the United States for commercial use are nifedipine and diltiazem hydrochloride.

At the recommended dosage, nifedipine, unlike verapamil hydrochloride, has no effect on the sinoatrial or atrioventricular node. In addition, it does not significantly depress myocardial contractility. It can, therefore, be used safely in patients with conduction abnormalities and congestive heart failure. Its major target tissue is vascular smooth muscle. Of the calcium channel blockers currently available, nifedipine is the most potent vasodilator. Its use in the emergency room is dependent on this effect. Nifedipine produces coronary artery dilation, rendering it very effective for treating vasospastic (Prinzmetal's) angina. Given sublingually, it is simple to administer and acts rapidly. Nifedipine also induces systemic vasodilation and is emerging as an effective drug for control of cases of hypertension in the emergency room. Unlike other calcium channel blockers, tachyphylaxis to its antihypertensive action has not been reported. For patients with diastolic pressures lower than 110 mm of mercury, 10 mg given sublingually or orally usually achieves good control. For diastolic pressures greater than 110 mm of mercury, 20 mg is given. An additional 10-mg tablet can be given after one hour if necessary. A mild increase in heart rate of approximately ten beats per minute may result.

Long-term use of nifedipine does not produce sodium retention, plasma volume expansion or renin release. Combining it with propranolol hydrochloride provides additional antihypertensive control, blocks the reflex increase in heart rate and permits twice-a-day dosage of nifedipine. Methyldopa can also be used but the nifedipine must be given every six hours. Mild pedal edema can be managed with the use of diuretics. Because vasodilation with subsequent afterload reduction decreases myocardial oxygen consumption, nifedipine is also effective in treating classical angina; it is infrequently used in emergency departments for this indication, however, because of the efficacy of nitroglycerin.

Diltiazem is the latest calcium channel blocker to be released. Its actions are intermediate to those of verapamil and nifedipine. Diltiazem is equivalent to verapamil in depressing atrioventricular node conduction, but produces less refractory period prolongation. Therefore, it is effective in treating paroxysmal supraventricular tachycardia and atrial fibrillation or flutter, but may be safer than verapamil in patients receiving digoxin or those with atrioventricular nodal disease. However, diltiazem has a greater inhibitory effect on the sinoatrial node and is more dangerous in patients who have sick sinus syndrome. Diltiazem is indicated for the treatment of cases of both types of angina, producing more vasodilation than verapamil but less than nifedipine. In addition, diltiazem has less negative inotropic activity than verapamil. Although possessing some theoretic advantages, diltiazem has not proved clinically superior to the other calcium channel blockers in the emergency setting. Therefore, it has no specific indication in emergency medicine at the present time. Except for its use in treating congestive heart failure, it has the same contraindications as verapamil.

None of the calcium channel blockers currently available are effective in cerebral salvage after cardiac arrest. However, newer calcium channel blockers, such as lidoflazine and flunarizine hydrochloride, have prevented neurologic deterioration after brief periods of global ischemia in laboratory animals. Studies are currently in progress evaluating their effects in humans.

Carl Schultz, M.D.
Orange, California

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New Diagnostic Tests of Blunt Cardiac Trauma

Myocardial contusion is an elusive clinical disorder. The absence of both a simple, accurate screening test and a diagnostic gold standard causes confusion. Moreover, no good clinical studies accurately define short- and long-term morbidity and mortality.

The workup of patients in an emergency department who have possible cardiac contusion includes a history, a physical examination and electrocardiography. The reported sensitivity and specificity for electrocardiographic prediction of cardiac contusion are variable and depend on the diagnostic criteria used. If the mechanism of injury is of high risk for cardiac contusion, the patient is admitted and CPK-MB isoenzyme studies are done. The presence of CPK-MB isoenzyme was initially thought to represent the gold standard for diagnosing cardiac contusion; recent reports, however, have shown a lack of specificity in patients with multiple trauma, even when CPK-MB ratios are used. Nevertheless, it does appear to be the most sensitive of currently used screening tests, and a clinical suggestion of cardiac contusion warrants that both an electrocardiogram (ECG) and CPK-MB values be obtained.

Radionuclide scans with technetium Tc 99m pyrophosphate have a low sensitivity for cardiac contusion and should no longer be used.

Recently, two relatively new diagnostic methods have shown promise: multiple-gated acquisition (MUGA) radionuclide scans and two-dimensional echocardiography. The MUGA scan is useful in determining whether continuing hemodynamic instability may be due to cardiac contusion.

Most patients suspected of having a cardiac contusion are young and otherwise healthy. Consequently, segmental wall dysfunction on MUGA scan is felt to be specific for cardiac contusion in young, previously healty trauma victims.

Advantages of the multiple-gated acquisition scan include

- Cardiac dysfunction caused by cardiac contusion can be documented and a patient appropriately managed;
- Serial MUGA scans document the course of hemodynamic compromise. In one large series 27 of 32 patients with abnormalities on a MUGA scan subsequently had improvement or resolution of their wall motion defect on follow-up scans, indicating recovery of the contused myocardium;
- The test is relatively noninvasive and can be done with a portable γ-camera in an intensive care unit.

Disadvantages of the MUGA scan include the following:

- Lack of 24-hour availability in most hospitals;
- Hypovolemia may cause the scan to be falsely positive due to decreased cardiac filling;
- Older patients with preexisting cardiac disease may have positive findings from nontraumatic causes;
- The predictive relationship between the scan's findings and morbidity and mortality has not been clearly established.

Two-dimensional echocardiography may prove to be of use in the future; a recent report indicates that two-dimensional echocardiography can detect complications of cardiac contusions.

Emergency physicians must continue to rely on "clinical suspicion" and ECG findings in screening patients with possible cardiac contusion. Identifying CPK-MB isoenzymes is best used to screen trauma patients requiring hospital admission. For hemodynamically unstable patients, portable MUGA scans can be done in an intensive care unit. With hemodynamic monitoring, MUGA scans provide the best current method for determining the presence of hemodynamic instability due to cardiac contusion.

C. Blake Schug, M.D.
Robert Knopp, M.D.
Fresno, California

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Conjunctival Oximetry

Maintaining adequate tissue oxygenation to prevent an aerobic cellular metabolism is a major function of the cardiorespiratory system. Clinical assessment of this important physiologic variable was not possible before the development of miniaturized polarographic oxygen electrodes that could be placed directly on peripheral tissue sites. Initially, transcutaneous oxygen sensors were used; these sensors required heating to liquefy the stratum corneum so that oxygen could diffuse from the subcutaneous capillary bed to the oxygen electrode. Transcutaneous sensors introduced artifacts in the measurement of tissue oxygenation because the heated electrode produced increased tissue metabolism, reactive hyperemia and a rightward shift of the oxyhemoglobin disassociation curve in the area beneath it. In addition, the prolonged stabilization period (longer than ten minutes) and the relatively slow reaction time to clinical events prevented widespread use of the transcutaneous oxygen sensor in emergency medicine.

The recent development of a conjunctival oxygen sensor has permitted direct measurement of tissue oxygenation ($Pcjo_2$) without heating artifacts. The miniaturized oxygen electrode is mounted on a polymethylmethacrylate ocular conformer, so that on insertion the electrode lies against the lateral, superior palpebral conjunctiva. Because no stratum corneum is present on the conjunctiva, an unheated oxygen electrode is used. The capillary bed is located about 30 microns from the conjunctival oxygen electrode and $Pcjo_2$ values have been calculated to be from 5 to 10 torr less than capillary oxygen tension. The conjunctival sensor can be rapidly inserted without patient discomfort, and can be left in place for up to 24 hours. Stabilization of the conjunctival sensor is almost immediate, so that meaningful values of conjunctival oxygen tension are available within 60 seconds of insertion. The response time of the conjunctival sensor to physiologic state changes is rapid, usually from 30 to 60 seconds.

In normovolemic patients with a normal cardiac output, $Pcjo_2$ is about 70% of partial pressure of arterial oxygen (Pao_2), and these two variables track each other closely. In this setting, $Pcjo_2$ can be used as a continuous, noninvasive monitor of Pao_2 and respiratory state.

Because the conjunctival sensor measures tissue oxygenation at a peripheral site where perfusion is affected at an early stage of physiologic instability, measuring the $Pcjo_2$ can identify important alterations in clinical state before other noninvasively measured variables, such as blood pressure, respond to the changing situation. Decreases in peripheral tissue oxygen delivery and perfusion due to factors such as hypovolemia or poor cardiac function will result in disassociation of $Pcjo_2$ and Pao_2.

In a series of normotensive trauma patients with no history of cardiac disease, a $Pcjo_2/Pao_2$ ratio of less than 0.5 predicted an intravascular volume deficit of 15% or greater. Normalization of the $Pcjo_2/Pao_2$ ratio—that is, to values greater than 0.5—occurred with volume resuscitation. Deterioration of previously stable $Pcjo_2$ values, presumably reflecting decreasing cardiac output, preceded cardiac arrest by three to four minutes in critically ill patients; return of a viable cardiac rhythm was accompanied by a rise in $Pcjo_2$ from the values present during cardiopulmonary resuscitation.

The $Pcjo_2$ provides a unique measure of physiologic state, capable of detecting alterations in a patient's clinical condition before traditionally measured indicators show changes. Conjunctival oxygen measurement represents a major advance in noninvasive monitoring.

Edward Abraham, M.D.
Los Angeles

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Viral Hepatitis Type B Vaccine

Viral hepatitis type B attacks an estimated 200,000 people a year in the United States. Although most patients recover completely, in 1% to 2% of those admitted to hospital, fulminant hepatitis develops and 6% to 10% become chronic carriers of the disease.

The eight-year-old viral hepatitis type B (HBV) vaccine consists of a non-disease-producing hepatitis B surface antigen (HBsAg) protein extracted from the plasma of asymptomatic carriers. Multiple purification processes effectively inactivate all other known infectious agents. The vaccine inhibits the occurrence of disease or modifies its manifestations if given before or during the incubation period.

The HBV vaccine is recommended as routine immunization for people at high risk for infection. These include health care workers in regular contact with blood or body fluids, especially surgeons pathologists, oral surgeons, dentists and hygienists; operating room, intensive care unit, hemodialysis unit and emergency room staff, and hematology and blood bank technicians and phlebotomists. Other high-risk groups include sexually promiscuous populations (especially homosexual men), intravenous drug users, hemodialysis patients, residents and staff of mental institutions, prisoners and residents of viral hepatitis type B endemic regions. It is recommended that the HBV vaccine be given to household and intimate contacts of acutely infected persons. Recommended postexposure prophylaxis for known exposure to viral hepatitis type B has recently been modified such that the vaccine should be given along with an initial dose of hepatitis B immune globulin (HBIG) (at a separate site) to patients at risk; subsequent doses of the vaccine are given at one and six months, while the usual second dose of HBIG is no longer required. A booster of vaccine is recommended after five years. The vaccine can also be given to neonates whose mothers are HBsAg-positive; the risk to the fetus should be negligible. Pregnancy should not be considered a contraindication for vaccination for women at risk.

No serious side effects related to the vaccine have appeared in more than 200,000 recipients since testing began. Pain at the injection site and low-grade fever have been the only side effects noted in controlled trials of HBV vaccine. No cases of hepatitis B or non-A, non-B hepatitis have developed from vaccination. Similarly, there is no evidence that *any* cases of acquired immunodeficiency syndrome (AIDS) have been caused by vaccine administration, and, indeed, the incidence of AIDS is less in vaccine trial recipients (composed of patients at high risk for AIDS) than in matched controls who received placebo.

Anne Chester, Ph.D.
Jerome Chester, M.D.
San Francisco

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Nonoperative Management of Fingertip Amputations

Nonoperative management of fingertip amputations has been described in the literature for more than ten years and has now become a generally accepted alternative to surgical repair. Nonoperative treatment—allowing a fingertip to heal by secondary intention—has achieved cosmetic and functional results that are consistently superior to split-thickness grafting techniques. Local flaps such as the Kutler V-Y flap, crossed-finger flaps and volar-advancement flaps offer early coverage of a finger, but the complication rate and long-term results are poorer than with nonoperative management. Superior results have occurred in prospective trials in which the wound was allowed to heal secondarily.

Nonoperative management provides the further advantage of preserving maximum finger length by removing the necessity in most cases of rongeuring back the exposed bone to provide skin coverage surgically. Nevertheless, some patients who need skin coverage to return to work may elect a surgical procedure, even if some further shortening of the finger is required.

The technique of nonoperative treatment involves debridement of nonvital soft tissue only, followed by an occlusive dressing (antibiotic, petrolatum gauze, gauze bandage) for 48 hours. Warm-tap-water soaking four times a day for 10 to 15 minutes is then instituted. The wound may be covered with two plastic bandages between soakings (one over the end of the finger, and the other around the first to keep it in place). The wound heals in two to three weeks in cases of pulp amputation and four to eight weeks in cases of more extensive injury involving exposed or protruding bone. In many cases, the patient can return to work in two to three days with a protective splint, if needed. Frequent bandage changes and soaking serve to remove any exudate and debris. The prophylactic use of antibiotics is generally not necessary except in grossly contaminated wounds. Joint stiffness can be prevented by active range of motion of all finger joints during soaking.

Healing occurs as soft tissue migrates over any exposed bone and is covered by the advancing epithelial margin. The result is a fingertip with normal epithelium except for a small linear scar. Amputation neuromas rarely, if ever, occur. Sensation is generally excellent, as is cosmetic appearance. Most complications are related to nail deformity, which most often occurs when a significant portion of the bone under the nail bed has been lost. Such deformities may be eliminated by removing the nail matrix entirely (either at the time of injury or at a later date) if a patient so desires.

Roy G. Farrell, M.D.
Orange, California
Bill Rappaport, M.D.
Tucson

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The Use of Activated Charcoal in Cases of Poisoning and Drug Overdose

Activated charcoal is widely used in treating cases of poisoning and drug overdose. A finely powdered product of the pyrolysis of wood pulp, the charcoal is "activated" by exposure to oxidizing gas at high temperatures to make a network of tiny pores. The total surface area of these pores is about 1,000 m^2 per gram of charcoal. Activated charcoal binds a variety of drugs and chemicals and thus may prevent their absorption from the gastrointestinal tract. The effectiveness of charcoal in preventing poisoning was shown by a French pharmacist in 1831 when he swallowed a lethal dose of strychnine along with 15 grams of charcoal without ill effect.

Charcoal (50 to 100 grams) is routinely given to poisoning victims after emptying the stomach with ipecac-induced emesis or gastric lavage. Unfortunately, persistent emesis after ipecac is given often delays the administration of charcoal for as long as two to three hours. Because charcoal effectively binds many toxins, it has been suggested that simple administration of charcoal may eventually supplant ipecac-induced emesis in most poisoning victims. In fact, a recent study showed that the use of oral charcoal alone was superior to ipecac-induced emesis. Volunteers who ingested 2 grams of aspirin absorbed significantly less salicylate when treated only with activated charcoal compared with those who were given only ipecac. A third group treated with ipecac then charcoal showed aspirin absorption similar to the ipecac-only group. This was apparently because only two of ten receiving ipecac then charcoal were able to retain the charcoal due to persistent vomiting. Further studies will be needed before charcoal replaces emesis in routine poisoning management. Charcoal does not effectively bind some toxins, such as iron and probably alcohols. Also, the use of charcoal remains controversial in a case of acetaminophen ingestion when oral administration of the antidote, *N*-acetylcysteine, is contemplated.

Recently, interest has focused on the use of repeated doses of charcoal (15 to 20 grams every three to four hours) to enhance the elimination of some drugs and poisons. This may occur by interrupting enterohepatic or enteroenteric recirculation. A 50% reduction of the serum half-life of theophylline and phenobarbital has been recently found in volunteers given repeat-dose charcoal. To prove that orally administered repeat-dose charcoal does not simply bind unabsorbed ingested drug, Berg and coworkers gave volunteers phenobarbital intravenously and found the same reduction in serum half-life. This increased nonrenal elimination is thought to be due to a "back-diffusion" of drug across the intestinal villi to the intraluminal charcoal, resulting in what has been described as "gastrointestinal dialysis." A similar reduction in serum half-life with repeated-dose charcoal has been shown in patients overdosed on theophylline and phenobarbital. However, whether this has practical clinical benefit remains unknown. In a randomized study of phenobarbital overdose, for example, patients receiving repeated-dose charcoal awoke and were extubated no sooner than those getting a single dose of charcoal, even though the drug's elimination half-life was much shorter.

These findings are applicable to the management of poisoned patients. Orally administered activated charcoal remains a fundamental adjunctive therapy for gastrointestinal decontamination. It may eventually replace the use of ipecac as the best single treatment for a variety of ingestions. The contribution of the use of chathartics, emesis or lavage to gut decontamination remains unclear but each continues to be widely used. Repeated-dose charcoal enhances the elimination of several drugs and is currently recommended for over-doses of digitoxin, phenobarbital or theophylline.

Timothy E. Albertson, M.D., Ph.D.
Sacramento, California
Kent R. Olson, M.D.
San Francisco
C.J. Fisher, Jr., M.D.
Sacramento, California

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Large-Volume Fluid Resuscitation

The traditional approach to resuscitating exsanguinating patients has called for multiple large-bore intravenous catheters. In the past five years the means to achieve higher flow rates and fewer intravenous (IV) sites have been reexamined.

Flow rates are linearly and inversely proportional to tube length, linearly proportional to pressure and logarithmically (to the fourth power!) proportional to the radius of the tube's lumen. These considerations have led to new intravenous strategies described herein.

The Seldinger (wire-guided) catheter, used in intensive care units, probably represents the single greatest advance. Using an 18-gauge needle, an obturator allows, with technical ease, step-up to an 8.5 French sheath. This sheath can be inserted into virtually any deep or superficial vein as long as it is not subject to bending (kinking or venous perforation may then occur). An experimental 14 French sheath with an internal diameter (ID) of 4.5 mm (French number divided by 3 equals the millimeter) has been used without adverse effect in the veins of dogs. Y sidearms are often a part of catheter sheaths. Though originally small bore, many are now manufactured with internal diameters to match the catheter sheath. This allows their successful use in volume resuscitation.

Because standard IV tubing for administering blood has an internal diameter of 3.2 mm, the tubing becomes a limiting factor when catheter sheaths much exceed 8.5 French (2.7 mm ID). Thus another strategy has been to increase tubing size. Though not yet commercially available, tubing of 6.4 mm ID has been tested in concert with an 8.5 French catheter sheath. Even though the internal diameter of this sheath (2.7 mm) is less than that of standard IV tubing (3.2 mm), flow was considerably enhanced by this system.

Another major advance has been the routine use of pressure infusion bags placed about the plastic IV bags. These simple, inexpensive and trouble-free devices safely increase infusion pressures to 300 mm of mercury. Their use increases flow rates two to three times over simple gravity flow. Experimentally, infusion pressures of 600 mm of mercury have been used in vitro. Current pressure infusion bags "red line" at 300 mm of mercury, though this cutoff point appears arbitrary.

Other innovations have been described. To accommodate the large flow through a 14 French catheter, a manifold fed by five IV systems has been described and operated successfully in dogs. The Bentley autotransfusion system has been used in concert with the 8F catheter sheath to produce flows two to four times those achievable by gravity alone.

The size of the vein cannulated is probably only rarely the limiting factor in flow rates, due to the considerable ability of veins to dilate. However, in an exsanguinated patient, the larger vein is clearly easier to cannulate. Thus use of the femoral vein has been described more often recently, with initially encouraging results. Removing vein size from consideration, a recent communication describes successful placement of the IV tubing directly into the right atrial appendage at open thoracotomy.

The current optimal results with these developments are as follows: Using a pressure infusion bag at 300 mm of mercury, standard IV tubing and an 8.5 French catheter, in vivo flow rates of 500 ml per minute are achieved. Experimentally, using the same catheter with 6.4 mm tubing under 600 mm of mercury pressure, flow rates in vitro of crystalloid exceeded 3,000 ml per minute!

A word of warning: In the confusion surrounding the resuscitation of an exsanguinating patient, massive volume overload becomes a real danger. Therefore, careful ongoing evaluation and monitoring of intravascular volume are mandatory

Robert H. Dailey, M.D.
Oakland California

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Diagnosing Cases of Ectopic Pregnancy

Ectopic pregnancy is the leading cause of maternal death in the first trimester of pregnancy. The total number of cases of ectopic pregnancy reported in the United States rose from less than 18,000 in 1970 to greater than 52,000 in 1980. Ectopic pregnancy is extremely difficult to diagnose clinically. More than half of all cases of ectopic pregnancy are missed at first presentation, more than two thirds of ectopic pregnancies are ruptured at the time of diagnosis an 10% to 20% of patients suffer hypovolemic shock before definitive treatment is obtained.

Ectopic pregnancy must be suspected in all women of childbearing age presenting with either abdominal pain, irregular vaginal bleeding or both. While physical examination alone is unreliable in diagnosing ectopic pregnancy, culdocentesis has been found to be positive in from 75% to 94% of cases.

The two-minute agglutination-inhibition slide test for human chorionic gonadotropin (HCG) in urine remains negative until more than 1,500 mIU of HCG per ml is present, and from 30% to 50% of cases of ectopic pregnancy will be missed. The two-hour slide test is more sensitive (positive at greater than 250 mIU HCG per ml) but as much as 10% to 20% of cases of ectopic pregnancy may still be missed. Qualitative serum βHCG assays are currently available, inexpensive, require only 30 minutes to do and give a positive report at a serum level of greater than 35 mIU HCG per ml. In a recent review of the literature, this test was positive in 439 of 445 (98.7%) cases of ectopic pregnancy. Quantitative serum β-HCG assays measuring levels less than 25 mIU per ml exist but are not widely available and require much longer to do.

Real-time ultrasonography is of great help in establishing the diagnosis of unruptured ectopic pregnancy. Its primary role lies in documenting a normal intrauterine pregnancy at about five to six weeks of gestation. Such a finding essentially excludes the possibility of ectopic pregnancy because the incidence of coexsisting ectopic pregnancy and intrauterine pregnancy is about 1 in 30,000 pregnancies. Ultrasound examination may be of secondary importance in supporting a diagnosis of possible ectopic pregnancy by showing an adnexal mass or fluid within the cul-de-sac, or both. The ability to identify an adnexal mass as an ectopic pregnancy rather than a large ovarian cyst, hydrosalpinx, tubo-ovarian abscess or other cause of adnexal enlargement varies from center to center.

When a case of ectopic pregnancy is suspected, culdocentesis should be done. Positive findings on culdocentesis warrant a gynecologic consultation. A negative or nondiagnostic culdocentesis should be followed by pregnancy testing. A rapid two-minute urine pregnancy test that is positive should be followed by pelvic ultrasound examination. An ultrasound examination that does not show a normal intrauterine gestational sac should be followed by laparoscopy. If the two-minute urine pregnancy test is negative it should be followed by a serum β-HCG test. A negative β-HCG test rules out an ectopic pregnancy in all but about 1% of cases. A positive β-HCG test should be followed by pelvic ultrasound study or laparoscopy. In one recently published study in which such an approach was used, all 16 patients with ectopic pregnancy from a study group of 81 patients suspected of having the disease were successfully identified.

Robert S. Hockberger, M.D.
Torrance, California

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Limb-Sparing Treatment of Adult Soft-Tissue Sarcomas and Osteosarcomas

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Introduction

Soft-tissue sarcomas and osteosarcomas are relatively rare tumors that represent less than 2 percent of all new cancer cases occurring each year in the United States. The number of new soft-tissue sarcomas and malignant bone tumors diagnosed yearly is 4,800 and 1,900, respectively, according to American Cancer Society estimates. Clinical advances in the treatment of these tumors have been hampered by the difficulty of accruing adequate numbers of patients in valid prospective therapeutic trials.

Surgical resection has always had a major role in the treatment of the primary lesion in adult patients with either soft-tissue sarcoma or osteosarcoma of the extremities. Amputation of an extremity has been a relatively frequent choice of resection for soft-tissue sarcomas in the past because of high local treatment failure rates when wide surgical margins could not be achieved by a limb-sparing resection as the only treatment. For osteosarcomas in the extremities of both young and older adults, amputation has been the mainstay of treatment of the primary extremity lesion in most patients. The recognition of the possible role of radiation therapy and/or regional or systemic chemotherapy in the treatment of both soft-tissue sarcomas and osteosarcomas has raised many questions regarding the preoperative evaluation, extent of surgical resection required when these modalities are employed, the results of this treatment in comparison to amputation, and the optimal treatment strategy.

In an effort to resolve some of the questions surrounding these issues, the National Institutes of Health convened a Consensus Development Conference on Limb-Sparing Treatment of Adult Soft-Tissue Sarcomas and Osteosarcomas on December 3-5, 1984. During a day and a half, presentations were made by experts in the field who reported their experience with the management of over 2,000 patients with high-grade extremity sarcomas. A consensus panel drawn from the medical and allied health professions considered the evidence and agreed on answers to the following key questions:

1. What is the optimal pretreatment evaluation of the high-grade sarcoma patient regarding diagnosis, extent of disease workup, and staging?
2. Are there types of patients for whom limb-sparing treatment should be considered appropriate therapy?
3. If so, what is the optimal limb-sparing treatment strategy? Consider the following: indications and contraindications, extent of surgical resection, need for and form of radiation therapy and/or chemotherapy, treatment morbidity and function of the limb, and end results.
4. Are there types of extremity sarcoma patients for whom adjuvant chemotherapy is indicated?
5. What directions should be taken for future research on the treatment of extremity sarcomas?

It should be stressed that the panel considered only issues related to high-grade soft-tissue sarcomas and osteosarcomas since low-grade sarcomas do not pose the major problems addressed in this conference.

Panel's Conclusions

High-grade extremity sarcomas are life-threatening or potentially disabling neoplasms that require aggressive management by an experienced multidisciplinary team. Data reviewed from recent clinical experience have shown the feasibility and appropriateness of limb-sparing treatment for a significant proportion of these patients. The

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

concepts of limb-sparing treatment for some of these sarcoma patients is a clearly established treatment option, but questions remain regarding optimal therapeutic strategies.

1 . **What is the optimal pretreatment evaluation of the sarcoma patient regarding diagnosis, extent of disease workup, and staging?**

Diagnosis and Pretreatment Evaluation of Soft-Tissue Sarcoma and Osteosarcoma

Soft-Tissue Sarcoma – Diagnosis is established by a biopsy, following identification of a mass. The biopsy site should be located and oriented so as to be incorporated into the subsequent definitive excision with the least sacrifice of normal tissue. The biopsy should be adequate to allow full histologic evaluation. In some instances, this will require the use of special techniques such as electron microscopy or immunohistochemistry.

The dimensions of the primary disease and regional extensions can best be determined in extremity sarcomas by contrast-enhanced CT scan. Supplemental arteriography in certain cases may better define the exact relationship of the primary sarcoma to the vascular system. If the tumor is located in proximity to bone, conventional radiographs are required; when questionable bone involvement is present, radionuclide bone scan may be useful. A chest X-ray must be taken to evaluate metastatic disease, and a CT scan or tomograms of the lungs are recommended in the face of a negative chest X-ray.

Osteosarcoma – Presumptive diagnosis of bone sarcoma is generally made by conventional diagnostic imaging, usually radiographs. The minimum criteria for pretreatment evaluation should include biplanar conventional X-rays of the local lesion and a radionuclide bone scan to evaluate the possibilities of multicentric and/or metastatic disease as well as the extent of the disease within the involved bone. Prior to definitive surgical treatment, a CT scan of the involved limb should be obtained to evaluate both intraosseous and extraosseous extent of disease. The use of contrast media in association with the CT scan is helpful in delineating the extent of the disease relative to the vascular system, and this may be supplemented by an arteriogram when indicated. Conventional PA and lateral chest radiographs and a CT scan of the chest (or tomograms of the lungs) to increase screening sensitivity are considered necessary.

A histologic diagnosis is considered essential prior to treatment planning. Depending on the location of the tumor, and the expertise of the available pathologist, either an open or a needle biopsy should be performed. The biopsy technique itself is critical to a successful outcome, and the same considerations expressed for soft-tissue sarcoma apply here. There are certain sarcomas of bone that should be treated with a one-stage excisional biopsy, specifically the juxtacortical (parosteal) osteosarcoma, where the radiographic characteristics should define the extent of the tumor prior to surgical intervention.

Staging Systems

Staging is necessary to plan appropriate treatment, provide a prognosis, and allow comparison of varying therapeutic strategies. Histologic grading of the tumor is an integral part of all staging systems for sarcomas. The criteria for histologic grading in soft-tissue tumors have not been well defined, or generally accepted, and vary based on a number of determinants such as histologic subtype, frequency of mitosis, and degree of necrosis. Recent reports from two separate laboratories suggest that the combination of histologic type and degree of tumor necrosis in soft-tissue sarcomas can predict metastatic potential. In contrast, bone sarcomas are graded on their histologic and radiographic appearance.

In addition to grading, the extent of local and/or distant disease must be included to provide some correlation with treatment choice and prognosis. Currently, the staging systems endorsed by the American Joint Committee (AJC) and the Musculoskeletal Tumor Society assign varying degrees of significance to these determinants. The AJC staging system assigns three histologic grades to the tumor, which dictate the stage of disease in nonmetastatic cases, with modifiers for each histologic grade based on tumor size. The Musculoskeletal Tumor Society grading system assigns only two histologic grades and modifies these based on anatomic location of the tumor. Neither of these systems is without drawbacks, yet both have positive correlations with survival. Until a unified staging system can be developed, results of therapy for these tumors, including limb-sparing surgery, should be reported in terms of both systems.

2 . **Are there types of patients for whom limb-sparing treatment should be considered appropriate therapy?**

Yes. Multiple studies reported from major medical centers have shown that control of disease in both high-grade soft-tissue sarcomas and osteosarcomas can be achieved with surgical resection less than amputation in a significant proportion of patients. Some patients, previously requiring amputation, can now undergo limb-sparing operative procedures without jeopardizing the end result in terms of either local or distant disease control. These results often have been associated with the concomitant use of radiation therapy and/or regional chemotherapy. This general approach is clearly appropriate at the present time for a significant proportion of carefully selected adult patients with high-grade soft-tissue sarcomas and osteosarcomas, when treated at facilities that possess the required technology and expertise. However, the optimal use of multimodal therapy is not yet established for patients with high-grade extremity sarcomas.

3 . **If so, what is the optimal limb-sparing treatment strategy? Consider the following: indications and contraindications, extent of surgical resection, need for and form of radiation therapy and/or**

chemotherapy, treatment morbidity and function of the limb, and end results.

Indications and Contraindications

Limb-sparing surgery is a procedure that removes a soft-tissue or bone sarcoma while preserving the extremity with a satisfactory functional and cosmetic result. All of the investigators reported to the panel that limb-sparing surgery is the preferred approach in the management of patients with high-grade soft-tissue sarcomas when local disease can be completely resected. Because of the risk of local recurrence, other therapeutic modalities may be used in conjuction with surgery, such as 1) preoperative radiation therapy, 2) preoperative chemotherapy, 3) postoperative radiation therapy, 4) postoperative chemotherapy, or combinations of these adjuvant treatments.

There are situations when limb-sparing surgery for soft-tissue sarcoma may not be indicated. These include the following:

- Lesions of the extremities in which it is impossible to achieve adequate surgical margins and when radiotherapy cannot be added without risk of major radiation therapy complications.
- Primary lesions that involve major vessels and nerves, either at the proximal extremity or in a site that will critically compromise function.

For patients with osteosarcoma, potential candidates for limb sparing must have tumors in an anatomical location that will allow complete resection with clear surgical margins. Reconstruction following resection should provide limb function that is equal to or superior to the function of a prosthetic device. Reasonable expectation for weight bearing in the lower extremities and functional use of the hand after surgery are prerequisites for limb-sparing surgery. Some patients who did not initially fulfill the above criteria have become suitable candidates for limb-sparing surgery following preoperative chemotherapy.

Limb-sparing surgery for osteosarcoma is contraindicated when the extent of a tumor is such that a clear surgical margin cannot be achieved and still allow a functional limb; in such situations, amputation is indicated. In some centers, this determination is made at the time of initial presentation, while other groups evaluate lesions after one or more cycles of chemotherapy. Metastatic disease is not necessarily a contraindication for limb-sparing surgery.

Children under the age of 10 years with osteosarcoma and anticipated growth remaining in the unaffected limb are generally considered for amputation. With limb-sparing surgery, they would have a limb length discrepancy inadequate for function when resection of the tumor includes the growth plates in the involved extremity.

Extent of Surgical Resection

The extent of surgical resection for limb-sparing surgery in soft-tissue sarcoma requires a microscopic-free margin for optimum control of disease. Surgical resections may vary from radical compartment removal to marginal excision, depending on the location and size of the tumor, age of the patient, and stage of disease. Limited resection margins dictate the need for regional radiotherapy. Apposition of the sarcoma to periosteum or neurovascular structures does not necessarily eliminate the possibility of a limb-sparing procedure, providing reasonable limb function can be achieved by reconstructive alternatives that will be required following adequate resection.

For osteosarcomas, it is generally accepted that *en bloc* resection of tissue should yield a clear surgical margin. All dissection should be performed in normal tissue outside the reactive zone of the tumor; however, the margin of normal bone resected proximal or distal to the tumor has not been clearly defined, nor is there uniformity of opinion relative to the need for extra-articular resection in metaphyseal lesions.

Reconstructive alternatives following resection include a variety of complex procedures. Soft-tissue reconstruction in certain anatomic locations is acceptable, while some mechanical correction is required when stability is essential for function. The choice available for replacing bone and/or joints include internal prostetic devices, allografts, and arthrodesis. The selection of the optimum methods of reconstruction are currently under evaluation in several centers.

Need for and Form of Radiation Therapy and/or Chemotherapy

Soft-Tissue Sarcomas—In some centers, regional (intra-arterial) chemotherapy in combination with radiation therapy and surgery has been used in limb-sparing treatment of soft-tissue sarcomas. The results of this approach have not been established as superior to other multimodality approaches.

In many cases, radiation therapy plays an integral role in the limb-sparing treatment of soft-tissue sarcomas. Various centers have employed radiation preoperatively while others have used postoperative therapy; to date, there is no evidence to suggest an advantage of one treatment approach over the other, and both are considered acceptable. Preoperative radiation therapy may allow for limb-sparing treatment of marginally resectable or large tumors that otherwise would have required amputation.

The volume of the extremity that requires radiation is controversial. Some centers favor treatment of the tumor bed with wide margins, while others feel that the entire muscle compartment should be irradiated. Most experts feel that special attention must be paid to the following areas:

- Shrinking fields should be employed to limit the highest dose of radiation to the area of greatest risk for tumor persistence, and surgical clips placed at the time of resection facilitate accurate definition of this area.
- A longitudinal strip of normal tissue along the limb must be spared to minimize radiation-induced edema.

- Precise immobilization and shaped fields are important to ensure reproducible treatment and optimal results.
- Most radiation oncologists deliver doses of 5,500 to 6,500 cGy over a period of 5½ to 7 weeks.

Osteosarcoma—Virtually all centers treating osteosarcoma with limb-sparing surgery employ some form of adjuvant chemotherapy. Clinical trials combining limb-sparing surgery plus intra-arterial and/or intravenous chemotherapy have shown comparable survival rates compared to trials employing amputation plus chemotherapy. To date, there are no studies suggesting a superiority of intra-arterial over intravenous chemotherapy, and both are acceptable.

One institution also employed low doses of radiation therapy immediately following intra-arterial chemotherapy. It remains to be proved whether this radiation therapy has a beneficial effect.

There is evidence to suggest that some form of adjuvant treatment is beneficial in limb sparing treatment of osteosarcoma. Local recurrence appears to be reduced when adjuvant therapy is added before or after operation. In addition, the majority of patients who received preoperative regional chemotherapy with or without radiation had greater than 90 percent tumor necrosis in the surgical specimen.

Treatment Morbidity and Function of the Limb

Patients who undergo limb-sparing surgery for either soft-tissue sarcoma or osteosarcoma may experience early and late complications. For both, the primary surgery may be complicated by serious wound healing problems, infection, pathological fracture, and necrosis. Occasionally, these problems require further resection or subsequent amputation. The incidence of these complications may be reduced with refined surgical and radiation therapy techniques and appropriate rehabilitation.

In osteosarcoma, if the initial surgery is followed by or includes reconstruction with an internal prosthesis, complications may include fracture above or below fixation points, nonunion, or mechanical failure of the prosthesis.

In both groups of patients, ongoing functional concerns include restrictions in range-of-motion, pain, edema, decreased stability, deformity, inadequate strength, and emotional acceptance. In many patients with soft-tissue sarcoma, these limitations appear to interfere minimally with function and lifestyle; however, for others, significant changes may be necessary. Some patients with osteosarcoma require the use of prosthetic and orthotic devices and walking aids to accomplish activities of daily living. However, employment choices, lifestyle, and activity level may have to be altered.

Patients who receive intensive chemotherapy as part of the limb-sparing treatment plan may experience moderate to severe morbidity (e.g., myelosuppression, electrolyte abnormality, cardiomyopathy) and occasional treatment-related mortality. The long-term sequelae of multi-drug chemotherapy are not yet fully known.

Radiation therapy may also be associated with serious long-term morbidity, including, on occasion, severe fibrosis or necrosis and, rarely, radiation-induced secondary malignancy. Radiation directed to the upper thigh in young men will produce low-dose scatter radiation in the testes and has been reported to reduce sperm counts in some patients.

The psychosocial sequelae of limb-sparing treatment may clearly have profound effects on patients and families. Although data are not available, these issues are considered significant.

The management of treatment complications and functional limitations requires the close coordination of the entire health team. This team should include the surgeon, medical oncologist, radiotherapist, primary care physician, rehabilitation staff, nursing staff, social worker, and, most important, the patient and family. The team should address biomedical decisions, psychosocial issues, and all considerations that affect quality of life. Team collaboration and intervention should begin prior to treatment and continue throughout the patient's course.

End Results

For soft-tissue sarcoma, patients undergoing either adequate limb-sparing surgery, often combined with radiation therapy and/or chemotherapy, or amputation show similar disease-free and overall survival. The evidence for this includes a randomized prospective study where patients having limb-sparing surgery plus postoperative radiation therapy and chemotherapy were compared to patients undergoing radical amputation plus chemotherapy.

Disease-free survival and overall survival data for patients with osteosarcoma treated by limb-sparing surgery combined with adjuvant chemotherapy (and radiation in some instances) are similar to those of patients treated with amputation and adjuvant chemotherapy.

Pulmonary metastasis is the most common site of distal treatment failure for these sarcomas and is frequently amendable to surgical resection. For both soft-tissue sarcoma and osteosarcoma, resection of pulmonary metastases may lead to cure in a significant number of such patients if removal of all clinical evidence of metastasis can be accomplished.

4. Are there types of extremity sarcoma patients for whom adjuvant systemic chemotherapy is indicated?

The role of adjuvant systemic chemotherapy in the treatment of high-grade soft-tissue sarcoma of extremities remains unsettled. Several studies utilizing adjuvant chemotherapy have failed to demonstrate a therapeutic advantage, whereas one study has shown an increase in disease-free and overall survival. The efficacy of adjuvant systemic chemotherapy for high-grade soft-tissue sarcomas remains to be established within the context of prospective clinical trials.

Adjuvant systemic chemotherapy as a component of treatment for patients with osteosarcoma has been studied extensively over the past decade. Published reports using historical controls indicate a benefit for drug-treated patients. One published prospective trial, which randomized patients to adjuvant chemotherapy or no chemotherapy, indicated no difference in disease-free and overall survival between drug-treated and observed patients. However, both groups of patients demonstrated better results than the other published studies not utilizing adjuvant chemotherapy. These results led to two new prospective randomized trials using intensive multidrug chemotherapy. Both of these studies are showing an advantage in the disease-free survival for the drug-treated patients in analyses that were presented to the panel but are not yet published. Although further followup of these patients is required, the panel is optimistic that adjuvant systemic chemotherapy will ultimately prove beneficial to the well-being and survival of patients with osteosarcoma.

5. What directions should be taken for future research on the treatment of extremity sarcomas?

As a consequence of this review, several research issues have been identified that would significantly affect our success in the diagnosis and treatment of this group of diseases if progress in these areas was achieved. The panel endorses the following items for future studies:

- Uniform and reliable staging systems for sarcomas based on correlative prognostic data.
- Reproducible criteria for grading soft-tissue sarcomas and the development of a review panel of pathologists available for developing a registry.
- Magnetic resonance imaging (MRI) or other means of improving the pretreatment and followup assessment of patients with sarcomas.
- MRI and MR spectroscopy or other means of evaluating the effect of preoperative chemotherapy on the tumor, and thereby refining the treatment of program.
- Identification and evaluation of markers (e.g., antigens, monoclonal antibodies) for monitoring tumor response and recurrence.
- Types of musculoskeletal reconstruction including the appropriate application and relative benefits of prosthesis, arthrodesis, and allografts. Development of more durable prosthetic devices, including those for growing children.
- Optimal treatment prescriptions for adjuvant therapies (route and scheduling of chemotherapy, biological agents, and radiation therapies), particularly the role of adjuvant chemotherapy for soft-tissue sarcomas.
- Evaluation of quality-of-life issues for treated sarcoma patients.
- Identification of etiologic factors for soft-tissue sarcomas and osteosarcomas.

Members of the Consensus Development Panel were: Walter Lawrence, Jr., M.D., (Chair), Virginia; Laurence H. Baker, D.O., Detroit, MI; Charles M. Balch, M.D., Birmingham, AL; R.L. Scotte Doggett, M.D., F.A.C.R., Sacramento, CA; Edmund A. Gehan, Ph.D., Houston, TX; Margaret Adams Greenly, C.S.W., New York, NY; E. Douglas Holyoke, M.D., Buffalo, NY; Allen S. Lichter, M.D., Ann Arbor, MI; L. Robert Martin, M.D., Whittier, CA; Nicholas L. Petrakis, M.D., San Francisco, CA; Phyllis K. Teich, MA., R.P.T., Bayside, NY; Roby C. Thompson, Jr., M.D., Minneapolis, MN; Richard E. Wilson, M.D., Boston, MA; Stanley H. Winokur, M.D., Atlanta, GA.

Members of the Planning Committee were the following: Alfred E. Chang, M.D., (Chair), Bethesda, MD; John H. Edmonson, M.D., Rochester, MN; Eli Glatstein, M.D., Bethesda, MD; Itzhak Jacoby, Ph.D., Bethesda, MD; Timothy Kinsella, M.D., Bethesda, MD; Walter Lawrence, Jr., M.D., Richmond, VA; Martin M. Malawer, M.D., Washington, DC; Steven Rosenberg, M.D., Ph.D., Bethesda, MD; Elliott H. Stonehill, Ph.D., Bethesda, MD; Robert C. Young, M.D., Bethesda, MD.

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BEHIND THE FACE OF HYPERTENSION

HISTORY OF MEDICINE

Plaster of Paris—Its History, Functional Properties and Potential Complications

DAVID GIBSON, M.D. AND RONALD W. LINDSEY, M.D.

ABSTRACT—Plaster of Paris has long been one of the most commonly utilized yet least understood substances in medical practice. Despite its wide acceptance, a variety of complications have been attributed to its use. We have provided a brief history and description of plaster along with its hazards to improve the quality of its application.

Introduction

Plaster of Paris has long been accepted in the medical community and the various plaster preparations display a wide range of uses clinically. Orthopaedic surgeons are quite comfortable with the employment of plaster in stabilizing fractured or unstable long bones, joints, and spinal columns. Physical therapists often use plaster for splints or inhibition casts in the management of patients with cerebral palsy.[5] Podiatrists utilize plaster as a conservative means of treating cutaneous ulcerations.[6] The vascular surgery literature notes that the immobilization of amputations with rigid plaster constructs hastens stump healing thus shortening the time to ambulation with a temporary prosthesis.[7]

What is Plaster of Paris? How is it prepared, and what happens when a cast hardens? Who was the first to use plaster? What are the major complications of plaster use? Although well molded casts and splints made of Plaster of Paris are applied daily, few physicians truly understand the substance, its history, composition and the potential complications of its use. We have endeavored to explore the history and functional properties of Plaster of Paris to improve both our understanding of this material and our ability to apply it more effectively. Contrary to popular beliefs, numerous complications can possibly result from plaster use, and are principally due to excessive heat, pressure, and moisture. We will explore each of these potential problems more closely, examine methods of early detection and suggest ways to avoid these difficulties.

History

The ancient Egyptians were perhaps the first to use stiffened dressings for splinting extremities. Bandages of linen made relatively rigid by gum were used both medicinally as well as for embalmer's wrap.[1] Hippocrates describes using bandages made with waxes and rosins to splint fractures of the lower extremities. He advised that the splinting should be done only after the fracture had been adequately reduced, a tribute to the extreme rigidity of his preparations.[1] The Arabs were the first to concoct a more plaster like material for the treatment of fractures. Rhazes, a ninth century physician, used lyme and egg white to fabricate a cast which offered sufficient strength and resistancy to wear until fracture healing had been attained. This calcium oxide casting material was found to be irritating to the skin, and was subsequently replaced by calcium sulfate, the modern day Plaster of Paris.[2] European physicians were gradually exposed to plaster-like substances during military campaigns into Arabia, Egypt and India in the 1700's. Hubinthal, in 1816, attempted to formulate a feasible plaster-like dressing for splinting fractures in Western Civilization. In order to fabricate his cast, he mixed equal parts of Plaster of Paris with ground up blotting paper. This mixture was applied to the fractured extremity with a spatula. German physicians, Koyl and Kluge, altered this technique when they advised pouring liquid Plaster of Paris into a mold which surrounded a fractured extremity.[2] However this method proved to be quite cumbersome and for apparent reasons was not well received.

The technique of plaster application was dramatically altered in 1852 by Dutch army surgeon Anthonius Mathysen. His technique called for Plaster of Paris to be

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DAVID GIBSON, M.D., Resident; RONALD W. LINDSEY, M.D., Assistant Professor; both of the department of Orthopaedic Surgery, Yale University School of Medicine.

hand rubbed into a mesh cotton cloth and loosely rolled into bandages which could then be used to make casts. This method was used extensively during the Crimean war and throughout the early 1900's.[2] The major advantage was that these plaster rolls could be prepared in advance and easily transported. However in this early composition plaster would frequently fall away from the cotton meshwork during delivery or application, making it necessary to continually supplement the prepared rolls with loose plaster by hand. Despite being somewhat awkward, these rolls of loosely coated plaster bandages were deemed satisfactory and could be obtained in large quantities as late as 1952. Hardcoated Plaster of Paris rolls were first developed in 1927 and despite their obvious advantages many years transpired before it replaced the "loosely coated" plaster in popularity. This modern day product maintained the Plaster of Paris bound to the cloth by a binder, consisting of starches, gums and rosins.

Preparation

Plaster of Paris is derived from hydrocalcium sulfate or gypsum, the chemical formula I 2 $(CaSo_4 \cdot 2H_2O)$. This substance is found in nature often associated with rock salts. Gypsum is mined and transformed via a process called "calcination" to Plaster of Paris. Calcination is essentially the heating of gypsum to approximately 128° centigrade in order to drive off most of the water of crystallization. The chemical reaction of this process is $2(CaSo_4 \cdot 2H_20)\ (CaSo_4)_2 \cdot H_2O + 3H_2O$. Adding more heat to the calcination process removes more water molecules resulting in a powder like substance with little strength characteristics. The addition of water transforms Plaster of Paris causing it to swell and subsequently "set." Luck showed the actual setting process is the arrangement of hydrocalcium sulfate into an interlocking crystal network. This is an extremely exothermic reaction which, theoretically, dispenses as much heat as required to calcinate the gypsum originally.[11]

Following hydration, Plaster of Paris undergoes a process called curing which is the removal of excess water by evaporation over several days. Curing time is dependent on temperature, humidity, and, most importantly, adequate air circulation around the cast. When adequately cured, plaster approaches its optimal mechanical characteristics, discovered by Schmidt and Sumerset to occur when the water content of the plaster has dropped to 21% of this initial "hydrated" level.[4] It generally takes greater than 24 hours for the water content of a normal cast to reach this preferred level; however, this can be highly variable. Care should be taken not to stress the cast until this "dry state" has been reached. Luck felt that perhaps the most important time during the creation of a plaster cast is when the plaster is going from a liquid to a solid phase, a point in time he referred to as the *critical period.* Motion during this critical period results in an imperfect crystalline network of calcium sulfate and greatly weakens the ultimate strength of the cast. Clinically, this point commences "when the plaster has attained a consistency of thick cream," and terminates when "the plaster loses its wet glistening appearance or becomes grainy."[3]

Luck's experiemental model compared the compression characteristics of two types of plaster cylinders. The first group of cylinders were made with maximal protection during the critical period, while the second group was subjected to 25° bending during the critical phase of the setting process. The casts in the second group were immediately straightened and allowed to finish setting. Luck showed that the disturbed casts were only 57% as strong as the perfect cast when analyzed for compression characteristics. Casts bent during the fluid phase of plaster setting prior to the critical phase showed no reduction in strength.[3] This critical point in the setting of plaster varies from one commercial preparation to the other, and the addition of accelerants such as *salycidic* acid, zinc, magnesium, copper, iron or aluminum hastens the setting process. The setting process is slow with the addition of glue, or gum. In all cases, the dip water temperature can significantly affect the speed of plaster setting (the cooler the dip water temperature, the slower the setting process).[3]

Complications resulting from the use of Plaster of Paris are not frequent, but are often avoidable. Rare reports have mentioned allergic reactions, [19,20] ringworm infestation, [18] and abnormalities of focal hair growth.[21] The most common problems appear to involve either excessive heat, pressure, or moisture following casting, and merit a more in depth discussion.

Heat

The hydration of Plaster of Paris as in exothermic reaction with a significant heat of reaction. Although relatively rare, burns secondary to the application of plaster casts have been reported. Kaplan describes two cases of second and third degree burns secondary to upper extremity splints.[8] A similar case of plaster-related burns have been described by Grazmer and Decker.[10] Williamson and Scholtz showed that not only the absolute temperature, but also the time one is exposed to a given temperature is important in the reduction burns.[22] In their study a heater was applied to the skin of volunteer subjects, there was a linear relationship between skin temperature and the time at which burns were produced. These reactions were found to fall into three zones corresponding to first, second and third degree burns.

How the heat of reaction in plaster hydration relates to the production of burns in cast applications was illustrated in an experimental model by Pope and Lavalette.[11] They attempted to show the critical temperature level in conjunction with varying lengths of skin exposure time that would result in second and third degree burns. Pertinent variables in this experiment included temperature of the dip water, thickness of the cast, plaster residue in the dip water and impedance of heat dissipation by a circumferential pillow. A pyrex tube was filled with water at 36° to 30° Centigrade. It was then covered with a stockinette and one layer of webril padding. Plaster wrap was then applied in thicknesses of 8, 12, and 16 layers. This plaster was dipped in water of 24, 32 and 40 °C, with and without 10% plaster residue. A temperature time curve was plotted using temperatures measured at the plaster-pyrex interface, at the inside of the plaster cylinder and on the outside of the cast.

The experiment demonstrates three factors that are important to potential skin burns in the applications of casts:

1. dip water temperature of more than 34 ° leads to faster setting and more intense production of heat,
2. cast thicknesses of greater than 8 piles of plaster leads to greater heat production over a longer period of time,
3. inadequate ventilation of the drying cast precludes dissipation of heat thus exposing the patient for a longer period of time at a given temperature. These factors are even more applicable to fast drying plaster preparation which have a higher peak temperature while setting. Synthetic casts have recently been shown to not generate as much heat while setting, with the likelihood of thermal injury being less than with Plaster of Paris.[23]

Pressure

Excessive pressure created by Plaster of Paris casts, either diffused or localized, has long been recognized as a source of numerous complications. Local pressure can result in: 1. skin breakdown. 2. nerve palsies or 3. major vascular compromise. Common cutaneous pressure areas in lower extremity casting includes the areas overlying the anterior superior iliac spine, the greater trochanter, the fibula head, and the heel. In the upper extremity the radial styloid, epicondyles, the olecranon are at greatest risk. Extra cast padding should be applied to these bony prominences. Often poor application technique results in wrinkled cast padding and local indentations in the plaster which can also cause skin breakdown even in areas where bony prominences are not present. Generally it is preferable to window a cast whenever a patient is complaining of localized burning pain, especially in highly susceptible sites. If ignored full thickness skin loss may occur resulting in problems with coverage and infection.

Nerve palsy is another frequent, but avoidable, complication. Peroneal nerve palsy is the most common paralysis a result of direct cast pressure and often due to the patient's lying with his leg externally rotated in bed.[12] Motor and sensory examinations of the ipsilateral foot should be performed daily, especially in the bed ridden patient. Any weakness in dorsiflexion or marked paresthesias of the foot warrants windowing of the cast over the fibula head. Ulnar nerve palsies are less common and they are generally the result of pressure on the nerve as it passes through the cubital tunnel. Similarly, treatment for this is release of the constricting cast at this region of bony confinement.

Vascular compromise is a potentially devastating affect of pressure in casting. Prolonged compromise results in tissue ischemia and necrosis with muscle being the initial tissue severely damaged. Hardy and Baddeley showed that compartment pressures can rise within the deep tissues of the thigh following application of cast braces in the treatment of femoral fractures. This elevated pressure, which can be up to 55 mm of mercury, higher in the casted patient, has been cited as essential in the maintenance of fracture fragment alignment.[13] Linson, Lewinnek, and White point out that this local tissue perfusion may be further diminished in patients with peripheral vascular disease. They presented two cases of elderly women whose underlying vascular disease was so severe that they could not tolerate the local skin pressure and the increased tissue pressure that cast braces generated, resulting in significant skin and soft tissue loss. They suggested that plaster be altogether avoided in patients with longstanding peripheral vascular disease.[14]

Another pressure related complication is the cast syndrome, a phenomenon that occurs with body casts. Narrowing of the angle between the superior mesenteric artery and the aorta due to pressure of the duodenum causes ischemia of the duodenum. This may result in ileus, gastric distension and gastric or duodenum perforation.[15] Direct vascular compression can result from casting acute fractures or an acute post operative extremity. This compression is a combination of circumferential, tight plaster application in combination with excessive swelling of the injured extremity. Cyanosis, numbness, tingling or excessive pain are all signs of vascular compromise and are causes for the immediate alteration of the cast. Although most clinicians are aware of these symptoms and the need for immediate action, there is some confusion over how to adequately treat these patients.

The question of how best to alter a cast to alleviate vascular compromise was explored by Ingold in 1979.[16] A model was devised using a fully inflated inner tube upon which a well padded plaster cast was applied. The inner pressure was monitored when the plaster first partially, and then fully cut (longitudinally). Pressures were also obtained when the underlying cast padding was partially, then fully spread (widely univalving the cast). The final pressure determination was obtained when the plaster *and* cast padding were entirely removed from half of the inner tube (essentially leaving a posterior splint). The lower pressure recordings predictably occurred with the posterior splint. The next lowest pressure occurred with wide univalving of the cast through the cast padding. It was clearly demonstrated that there is not a significant decrease in pressure when *only* the plaster was split. It was necessary to split the cast *as well* as the underlying padding in order to significantly relieve pressure on the tube. These findings suggest that in the clinical setting, casts should be split widely through the padding to decompress the extremity.

Moisture

A disadvantage of Plaster of Paris is its inability to withstand immersion in water without disrupting its integrity. Soaking a cast is actually a reasonable alternative method to cutting a cast for its removal and should especially be considered in young children. The underlying padding, as well as the plaster, can retain moisture from cast application and perspiration. Bacterial overgrowth, skin maceration, fungal growth, insect larva infestation can be encouraged by this warm, dark and moist environment inside a cast.

Houang, Buckley, Williams and O'Riordan reported an outbreak of pseudomonas wound infections on the Orthopaedic Service at the London Hospital.[17] All 13 patients involved in this outbreak had casts applied in the operating room. The source of infection was eventually traced to two plaster buckets used for preparing the patient's casts. In speculating how significant bacterial counts could be achieved within a cast only briefly exposed to the pathogen, plaster casts dipped in contaminated water were applied to several volunteers. They found that bacteria could actually multiply in slowly drying plaster. Skin contamination was reported in all volunteers despite a thick layer of sterile cast padding between the cast and the patient's skin. Such reports have prompted the use of sterile water and basins for plaster preparations, especially in the operating room setting.

The issue of retained moisture inside a patient's cast is equally important in synthetic casts as people are often encouraged to cover them with a plastic bag while swimming and to blow-dry them if they inadvertently get wet. Marks et al reported a cast of microsporum gypsum within three weeks of synthetic short arm cast application for a torus fracture.[18] Needless to say, retained moisture within the cast padding further complicates general cast hygiene.

Summary/Conclusion

Plaster of Paris has been successfully employed in many aspects of medical care. Its current composition and utilization has varied very little since its introduction and refinement years ago. It is often considered a completely benign aspect of the medical armamentarium; however, many devastating, yet avoidable, complications have been noted with increasing frequency in recent years. We have attempted to provide a better understanding of Plaster of Paris and, also, a more complete appreciation of its hazards.

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Month in Washington

Congress Puts GME Bills on Fast Track

As potential savings items in the federal budget, proposals to drastically alter the way Medicare pays for graduate medical education are on the Congressional fast track and the field of candidates is growing.

Four legislative alternatives to the President's proposals have been introduced for consideration in the Congressional budget process which is now seriously bogged down in House/Senate conference.

Three of the contenders would limit residencies for foreign medical graduates and modify Medicare contributions to direct training costs, promoting primary care over specialty care training. The other would establish hospital grants that would be updated for inflation and adjusted up to a point for changes in the size of an institution's residency program.

In introducing the latter proposal, Ohio Republican Ralph Regula claimed the measure had "universal" support within the medical education community and privately some medical groups admit a preference for the Regula approach. They see it as less restrictive than the other legislative approaches and believe its adjustments for size make it preferable to the Administration's proposed freeze.

Among the other legislative approaches, witnesses at a recent Senate Finance Committee hearing appeared to favor a plan that has just been introduced by three Senate Finance Committee members, Sens. Robert Dole (R-KS), David Durenberger (R-MN) and Lloyd Bentsen (D-TX).

The plan (S. 1158) would freeze Medicare payments for health professions training costs in 1986 and in future years would limit the number of years of medical training Medicare would contribute to. It is in competition with a proposal by Sen. Dan Quayle (R-IN) that would condition Medicare payment on a fixed proportion of primary care residents and with one by Rep. Henry Waxman (D-CA) that would fund primary care residents at a higher level than other specialties. Quayle's bill has been approved by a subcommittee of the Labor and Human Resources Committee.

While the medical education establishment generally accepts the premise that primary care residencies should be encouraged, witnesses from 12 hospital, medical and academic organizations told Durenberger they are skeptical about plans that would base payment on a government's definition of primary care or of the appropriate distribution of residencies between specialties.

"A quota or fixed ratio (of physicians) is very difficult in a system in great flux," warned Louis J. Kettel, M.D., who is vice chairman of the American Medical Association's medical school section. "Flexibility is important as the market adjusts to diagnosis related groups" and as changes occur in the "boundaries of who is doing primary care," the University of Arizona Medical College dean added.

None of the witnesses, on the other hand, expressed outright opposition to the Senate Finance members plan, though most of the medical and academic groups agreed with Dr. Kettel's assertion that limits on the number of years of training Medicare will support should "not be adopted without assurances that adequate funding will remain available for residencies with long-term training programs."

Virtually every group favored S. 1158's elimination of Medicare funding for residencies filled by foreign medical graduates who are not U.S. citizens, although all urged that the provision be phased in to protect those institutions that are presently very dependent on FMGs. A majority of the groups, suggested that funding should be denied to American citizen FMGs as well and Congressional staffers say there is a good possibility that the bill will be altered to include both these recommendations.

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The Blues Release Transplant Criteria

The Blue Cross and Blue Shield Association has released a list of criteria that can be used to help plans select medical centers for heart or liver transplantations.

By limiting coverage to transplant centers with good track records, Blue Cross-Blue Shield plans can be assured the highest quality of care, the national association believes. "Providers with more experience . . . tend to be more effective than providers with less experience," according to the report, entitled "Criteria for Evaluating Institutions for Liver and Heart Transplants."

California Blue Shield is the first plan to apply selection criteria to transplant centers. It has been so successful that it has decided to apply similar selection criteria to percutaneous transluminal coronary angioplasty, obstructive sleep apnea treatments, lithotripsy, and other procedures.

Because other plans risk reprisal under antitrust laws, the national association has been hesitant to urge nationwide adoption of transplant selection criteria. The report advises each plan to examine its state statutes to see

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Prepared by the Washington, D.C. Office of the American Medical Association.

whether the use of selection criteria would violate restraint-of-trade provisions.

The sudden interest in evaluating the competence of transplant centers is prompted, in part, by the exponential growth in the number of transplant institutions. Nationwide, the number of heart transplants jumped from 180 to 320 and the number of liver transplants increased from 160 to 240 between 1983 and 1984. A recent report by the Battelle Institute found that 197 centers are ready to jump into the heart transplant business if federal coverage is provided.

The criteria face stiff resistance from the medical community which fears restrictions on where, when and how it provides care. A limit on the number of transplant centers stifles innovation by newer and less established centers, says the American Hospital Association. In addition, it creates a "Catch-22" situation where a center needs experience to qualify but must qualify to gain experience.

Similar limitations on coverage—attempted but defeated by Congress last year—would have given the Department of Health and Human Services (HHS) the authority to restrict coverage for transplants and other procedures to designated medical centers.

There are signs that the Reagan Administration is now considering a similar approach. At a May press conference, HHS Secretary Margaret Heckler said that heart transplantations may achieve a "medically acceptable" survival rate "only in medical centers where a critical mass of clinical expertise and experience has been gathered."

The guidelines place transplant centers into four different categories:

- "established" centers, performing at least 24 transplants in the past 2 years with survival rates between 70% and 85%.
- "emerging" centers, performing between 12 and 23 transplants in 2 years and having survival rates between 60% and 80%.
- "intermediate" centers, performing between 6 and 11 transplants. Because their survival rates are based on so few transplants, it is difficult to assess the quality of these centers, the report says. Blue Cross-Blue Shield plans should assess each center on a case-by-case basis.
- "early" centers, performing fewer than 6 transplants in 2 years. These centers must "prove themselves."

The guidelines also suggest criteria for evaluating the internal structure of a transplant center. Institutions should have a transplant surgeon who has received clinical training from another transplant center, they state. Additionally, an institution should be able to provide care before the transplant, after the transplant, and after discharge. It also should be able to provide safe and effective immunosuppressive therapy, with a staff well-trained in handling the special problems of these patients.

Experience is important, the report shows. Potential heart transplant centers should perform at least 500 cardiac catheterizations a year, 250 open heart surgical procedures a year, and percutaneous transvenous endomyocardial biopsies. Liver transplant centers should have a staff that is experienced in the treatment of hepatic disease.

Patient selection should be standardized, as well. Heart transplant centers should select patients based on National Heart, Lung, and Blood Institute (NHLRBI) criteria; liver transplant centers should select patients based on criteria set by the 1983 National Institutes of Health consensus conference.

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New Medicare Regs Freeze Fees, Shift Prices

In addition to freezing Medicare's base payment rates for 1986, new regulations proposed by the Reagan administration would also lead to significant shifts in the prices Medicare pays hospitals.

Thus far, the regulations have drawn attention mainly for the proposed rate freeze. Health Care Financing Administration officials have included an elaborate set of calculations that concludes rates were too high in 1985 and could be reduced by at least 2.85%. A rate reduction was rejected as "punitive."

In addition to the base payment rate, however, Medicare payments are based on the relative weight of the diagnosis related groups the patient is assigned to. The new regulations propose to rerank or recalibrate the weights of the system's 470 DRGs. This will significantly increase the price paid for some conditions such as cataract surgery and lens implants while decreasing payments for other conditions such as cardiac arrhythmia.

Published in the Federal Register on June 10, the regulations also would affect the price of some individual medical procedures by assigning them to a different DRG. They would bring alcohol and drug treatment centers into the prospective pricing system; create a new DRG for some bilateral joint procedures; and establish a process for making mid-year changes in the DRGs. Public comment would follow at the end of the year.

The new rules leave open the politically sticky issue of revising a wage index used to adjust DRG rates for local labor costs. A revised index proposed in the rules would lead to major payment increases for some hospitals while decreasing payments to others and it is slightly more beneficial to rural hospitals than urban hospitals.

Congress has directed that the new index be applied retroactively, however, and some hospitals would have to pay back enormous sums if this provision were applied. HCFA officials are asking Congress for advice on this issue and they hope Congress will eliminate the retroactivity clause.

Open for public comment only until July 10, the new rules would also freeze rates for hospitals that are exempt from the prospective payment system and from state rate controls. They would continue the transition from rates that are partially based on hospital specific and regional costs to one that is based entirely on uniform national rates. They do not include an adjustment for hospitals that treat a "disproportionate" share of elderly and indigent patients. They propose a new method of counting hospital beds and residents for adjusting payments to teaching hospitals.

The decision to impose the freeze through regulations has angered many Congressmen. Hospitals hope to play on this to win some adjustments. The for-profit Federation of American Hospitals has threatened to sue the federal government if the freeze is accomplished by regulation rather than legislation and the American Hospital Association has issued an alert asking all its members to protest the Administration's action. The AMA also has opposed the freeze on hospital rates.

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Super-PRO Awarded

A hotly-contested contract to monitor the work of the nation's 54 Peer Review Organizations has gone to SysteMetrics, a Santa Barbara subsidiary of the McGraw-Hill publishing firm.

The so-called Super-PRO contract had been sought by 15 bidders, including the Iowa and Kansas PROs, several PRO subcontractors and old PSROs, and the American Medical Association. An earlier bid request had been withdrawn and scaled down after bids from the AMA and three other organizations all exceeded the funding that Health Care Financing Administration officials had available for the contract.

Effective June 17, the $2 million SysteMetrics contract will run for 14 months, with a $1.3 million, 10-month renewal contingent on Congressional funding in fiscal 1987.

SysteMetrics expects to review 83,000 medical records as part of its contract to assess the validity of the PRO objectives and criteria and the ability of the PRO to make medical decisions that conform to those objectives and criteria.

A first level of review will be conducted by 20 employees of SysteMetrics. Cases questioned by the reviewers will be referred for physician review. The bulk of the physician review will be performed by National Medical Audit, a physician-owned review firm in San Francisco. Headed by psychiatrist Arnold Milstein, M.D., NMA has 30 physician members, all of whom are board-certified and hold positions in major teaching hospitals. In addition, four regional physician panels of three members each will be established to review claims where regional issues arise.

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Bills to Provide Medicare-Medicaid Coverage for Respiratory Care

Claiming that current rules "violate common sense," Rep. Ron Wyden, (D-OR) and Sen. John Heinz (R-PA) have introduced bills to provide Medicare and Medicaid coverage for respiratory care outside a hospital setting.

The legislation, the Home Respiratory Care Act of 1985, would provide coverage to respirator-dependent patients who had already been hospitalized for 30 days and who preferred to be treated at home or in a nursing home. It results from the disbanding of a federal board that had approved waivers that permitted Medicaid to pay for about 200 seriously disabled children and adults who had remained hospitalized because Medicare or Medicaid would pay for care inside the hospital but not at home.

The Reagan Administration says the board is no longer needed since states can obtain Medicaid waivers, but critics say that the waiver procedure is difficult and coverage for respirators and other services will remain unavailable in many states.

The issue also has led to hearings on pediatric home health care in the Senate Labor and Human Resources Committee and hearings are expected in the House Commerce health subcommittee.

The review board was formed after President Reagan called the nation's attention to the case of Katie Beckett, an Iowa child who remained hospitalized because Medicaid would not pay for a respirator in her home. HHS officials estimate that Medicaid would save about $50 million a year under the process.

Heinz and Wyden say their bill would enable about 2,200 hospitalized, respirator-dependent patients to go home and that it could save Medicaid $20 million a year. The measure would be at least cost-neutral to Medicare, according to the sponsors.

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PaPRO in Limbo

Federal officials' plans to sign a new Peer Review Organization (PRO) contract with the Pennsylvania Medical Society (PMS) have been thrown into limbo by an unexpected proceeding in a U.S. bankruptcy court in Harrisburg.

The court action provides at least a temporary reprieve for the Pennsylvania Peer Review Organization (PaPRO) which Medicare officials had sentenced to die on June 19. It came just one day before medical society officials were to meet with the Health Care Financing Administration on a final contract agreement under which PMS would assume the PRO responsibility for reviewing the care of hospitalized Medicare patients in the state.

PaPRO had signed the $18.3 million PRO contract in mid-October but then ran into start-up problems and claims processing delays which led HCFA to freeze some $1.9 million of PaPRO's funds. A federal district court, on grounds it had no jurisdiction, dismissed a PaPRO request that would have held up the termination and released the funds. An emergency hearing before an appeals court was also denied.

HCFA then set an official termination date of June 19 for PaPRO and initiated "sole source" discussions with the medical society. A "final" agreement was expected at meetings scheduled in Washington on June 21.

The plan went awry when PaPRO, on what was to have been its final day, went to the bankruptcy court to seek to have the termination of the contract stayed and the funds released in order to pay off its creditors, reorganize and stay in business. In making its case, PaPRO complained that HCFA has not properly followed a lengthy termination process spelled out in the PRO law and regulations.

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Cigarette Tax Poll: Keep the Tax High

A new Gallup poll has found that 75% of the American public believes the federal tax on cigarettes should be kept at 16 cents rather than cut back to eight cents.

The poll, which was conducted for the National Heart Savers Association, found that only 18% of Americans believed that the tax should revert to eight cents as scheduled for October 1. Seven percent of the more than 1000 people interviewed were undecided.

The poll comes at a time when Congress is considering at least 12 different cigarette tax measures. Five of the bills would increase taxes to 32 cents; five would hold the tax at 16 cents and, in some cases, then raise it annually by a percentage equal to the increase in the consumer price index. The stiffest proposal, by Rep. Anthony Beilenson (D-CA), would raise the rate to 40 cents per pack.

The bulk of the proposals (9) would earmark at least a portion of the increased federal revenues to the Medicare hospital trust fund.

Debate could come as part of the federal budget action if Congress is able to agree on a budget resolution. The Reagan Administration is opposed to that approach, however, and has said that the current 16 cents tax should be allowed to revert to 8 cents on October 1.

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Health Care Clearinghouse Bills Introduced

Legislation has been introduced in both the House and Senate that would establish a clearinghouse for data on services, systems, prices, and quality of health care.

The clearinghouse would be designed to help consumers and employers find and interpret information about health care. It would not collect or distribute actual data, but would tell consumers where they could find it.

"We need a health care system that's a free market for consumers, not a free ride for producers," said co-sponsor Sen. Albert Gore Jr. (D-TN). "A health care data clearinghouse will help to make health care more equitable, more accountable and, above all, more affordable." It would be utilized by consumers and small businesses that now lack the information needed to make prudent cost-containment decisions, Sen. Gore said.

The legislation—S. 1367 in the Senate and H.R. 2882 by Rep. Ron Wyden (D-OR) in the House—instructs the Secretary of the Department of Health and Human Services (HHS) to make grants for the establishment and operation of a clearinghouse. Each clearinghouse must establish an advisory panel with representatives of physicians, hospitals, insurers and other representatives of the health care community. In addition, a report on clearinghouse activities must be submitted to HHS once a year.

The clearinghouse would identify public and private organizations that have experience with the collection of aggregate health care data, collect information on their use of methods of analysis, and provide technical assistance in the use of these methods to the interested public.

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Commission on Bioethics Bill

A successor to the now-defunct President's Commission for the Study of Ethical Problems in Medicine has been introduced by Tennessee Senator Albert Gore Jr.

The proposed National Commission on Bioethics would examine issues presented by the application of new technologies to humans. For instance, its first task would be to report to Congress on the implications of human applications of genetic engineering.

A similar commission was proposed last year as part of the National Institutes of Health reauthorization bill, but died when President Reagan vetoed the legislation. The earlier Commission expired in 1982.

The Commission would be composed of 15 members, four with biomedical backgrounds and three in health care. The remaining members would be members of the public or representatives of law, ethics, and theology. These members would be appointed by a special 12-member Congressional Board on Bioethics, also established by the bill.

It would serve only as an advisory body; the commission would have no regulatory enforcement power. However, it would report to the Congress.

"The Commission will provide Congress with much-needed analysis of the many difficult bioethical issues that confront our society," said Sen. Gore.

* * * *

Supreme Court to Hear "Baby Doe"

Tackling one of the major medical issues in recent history, the Supreme Court has agreed to hear arguments next term on *AMA et al., vs. Margaret M. Heckler;* the so-called "Baby Doe" case.

The Court must decide whether the nation's civil rights statutes apply to the treatment of handicapped newborns—in other words, whether the anti-discrimination law covers medical decisions in the same way it covers transportation, housing, and employment decisions.

Lower courts have already ruled that it does not. Regulations that would have sent investigative squads into hospital nurseries to find violations of Section 504 of the Rehabilitation Act have been proposed twice—and rejected twice.

Since then, Congress has passed legislation saying that intervention is sometimes inappropriate: when death is imminent, when treatment is futile and inhumane, when treatment would not correct all of the infant's life-threatening conditions, and when the infant is chronically and irreversibly comatose.

If the Supreme Court justices decide that the anti-discrimination law does apply, hospitals risk losing all federal funding if found guilty of withholding care.

Administration of the current "Baby Doe" law—which is based on anti-child abuse legislation, not anti-discrimination laws—would not be changed in any substantial way, according to Justice Department officials. Whereas the child abuse legislation focuses specifically on state and local child abuse authorities, the anti-discrimination regulations targeted hospital administrators.

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Ban on 'Ecstacy'

A hallucinogenic drug called "Ecstacy" used by some psychotherapists was outlawed beginning July 1, the Drug Enforcement Administration (DEA) announced in June.

The drug, MDMA or "Ecstacy," has no accepted medical usage and high abuse potential, the DEA says. A ban was necessary to avoid "imminent hazard to public safety," according to DEA Administrator John C. Lawn.

The drug, whose scientific name is 3,4-methylenedioxymethamphetamine, joins the ranks of heroin, cocaine and LSD as a highly restricted "'Schedule I" drug. Possession of a "trace" of MDMA will be punishable by up to 15 years in prison and a $125,000 fine.

The ban has rekindled the debate over the use of psychoactive drugs in therapy, silent since Congress passed the 1966 Drug Abuse Control Amendments. Physicians have a right to research the therapeutic potential of mind-altering drugs, MDMA suppporters say.

Although it is difficult to determine the exact extent of medical usage, therapists and analysts estimate that between 35 and 200 physicians are currently using the drug on some patients.

A survey of 300 hospitals across the country found there have been eight emergency room visits and two deaths from MDMA since 1979. One death—a California psychoanalyst with a heart condition—occurred with a 200 milligram dose, well above the typical 50 to 110 milligram dose.

Although the drug has been patented since 1914 and was tested by the U.S. Army in the early 1950s, it has only recently gained notoriety. It is estimated that nonmedical use of MDMA has climbed from 10,000 doses in 1976 to 30,000 per month in 1985.

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Cyclamate Clears Another Hurdle

In the latest chapter of its regulatory story, cyclamate has been cleared of any direct link to cancer. But it may cause tumors in the presence of other carcinogens, according to a new study by the National Academy of Sciences (NAS) released in June.

The NAS panel found that "the weight of experimental and epidemiological evidence does not indicate that the artificial sweetener, by itself, is carcinogenic but it may be a promoter or cocarcinogen in the presence of other substances."

These mixed findings could delay approval of the product, banned since 1969. Its complex interaction with other substances needs further study, the NAS panel urged.

The report does not compare the banned sweetener with those of the other two artificial sweeteners now approved by the Food and Drug Administration (FDA). But a 1982 NAS review found that aspartame was non-carcinogenic and a 1978 review found that saccharin is a weak carcinogen and promoter in animals.

The new NAS report, requested by the FDA, says that the findings of two 1969 rat studies—which found an association between cyclamate and cancer—have not been repeated. Moreover, newer and better studies show no such link, it says. The panel recommended, however, repetition of some animal studies showing a promotional or cocarcinogenic effect of cyclamate. The findings of human studies were less clear, and more troubling. Two groups appeared to be at increased risk; women nonsmokers and women who used large amounts.

Several other countries—including Canada, France, Germany and England—still use the artificial sweetener.

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FDA Quack Squads Crack Down

The salesmen for "Bio-Line Catalyst Water" thought they had snagged new business; at their booth at a Pittsburg health expo last November, an interested customer read promotional literature and listened to a sales pitch which promised treatment of heart disease, arthritis and urinary tract disorders.

Instead, they got a tersely worded letter from the Food and Drug Administration (FDA), warning them against selling an unapproved new "drug," making misleading claims and giving inadequate instructions for use. Continued sales could result in seizure of the product, they were told.

The "customers"—actually, undercover officers of the FDA's new Fraud Branch—have exposed 12 other profiteers of unproven remedies. The FDA fraud squad plans to visit other health expos this year to gather information and seek evidence of inter-state sales of fradulent products.

Until last fall, the FDA had no formal program to combat health fraud. Quackery was growing increasing sophisticated and the agency was "overmatched . . . by too many quacks, too skillful at the quick change of address and product name, for the cumbersome procedures of FDA regulation," former FDA Commissioner Arthur Hull Hayes, M.D., said last year.

Now, six FDA employees are cracking down on worthless or dangerous products working through FDA's 150 branches around the country. In addition to their undercover trips to health expos, they are investigating steroids, "look-alike" drugs, Herbalife supplements, mail-order weight loss products, General Nutrition products, chelation therapy, health claims on Kellogg's bran cererals, and bulk ships of DMSO.

In addition, the agency has stepped up public education efforts to help consumer recognize products that are mislabeled, misrepresented, or potentially harmful.

* * * *

CBO Report Says Many Veterans Will Lose Benefits

The Reagan Administration's plans to change VA eligibility standards would deny hospital and outpatient care to an estimated 655,000 veterans, according to new Congressional Budget Office (CBO) data.

If the proposal is passed by Congress, no longer would the VA continue its 15-year policy of offering unlimited free care for all veterans. Instead, it would use a "means test" to restrict care to non-service-connected veterans.

Enactment of the means test would shift over to Medicare an estimated 30,000 patients needing hospitalization and 125,000 patients seeking outpatient care, CBO said. The remaining 500,000 patients who earn more than the means test cutoff but say they cannot afford medical care in non-VA facilities would be forced to go elsewhere.

The stricter eligibility standards would affect roughly 158,000 hospital discharges a year, Nancy M. Gordon of CBO recently told the Senate Committee on Veterans' Affairs. The plan would save the federal government $390 million a year, based on the projected costs of VA medical care under current practice. The net savings would rise to more than $1.4 billion by 1990.

A second proposal, which would require private health insurance plans to reimburse the VA for medical expenses incurred by their clients—would save an estimated $50 million in 1986, creating net savings of about $200 million by 1990. Only about 10% of non-service-related veterans still served by the VA would be affected if the means test were enacted.

The plan has met intense opposition by veterans groups and the insurance industry. Former VA chief medical director Donald L. Custis, M.D., predicts that patient cutbacks would close dozens of VA hospitals, reduce staff and compromise the quality of care.

* * * *

Cancer and the Atomic Vet

Veterans of the 1957 Nevada nuclear test blast called "Smoky" are dying from excessive rates of leukemia, but participants in five other nuclear test series show no increased mortality from cancer or other diseases, according to a National Academy of Sciences (NAS) report released in June.

In fact, mortality rates in men who took part in these series—code-named "Greenhouse," "Upshot-Knothold," "Castle," "Redwing," and "Plumbbob"—are less than those of the average population, the NAS researchers found.

Researchers found 10 cases of death from leukemia in the 3,554 "Smoky" participants, instead of the 3.9 cases they expected based on deaths in the general U.S. population—2.5 times the expected number of deaths. Of these 10 cases, there were 5 cases of acute myeloid leukemia, 2 cases of chronic myeloid leukemia, 2 cases of chronic lymphatic leukemia, and 1 case of acute lymphatic leukemia.

The findings confirm the results of a 1979 study by the Centers for Disease Control (CDC) on "Smoky" participants. But the surprise was that they are the only group of veterans who showed excessive mortality from a form of cancer known to be induced by ionizing radiation. Because of the low cancer incidence among other test participants, NAS researchers believe that the appearance of leukemia among "Smoky" participants could be a "chance aberration."

* * * *

HHS TV Spot to Educate Elderly on Drugs

"Use medications safely for a better life" is the tag line in a new public service announcement produced for the American Association of Retired Persons as part of a "Healthy Older People" program directed by the Department of Health and Human Service and involving a variety of state and logal governments, voluntary groups and businesses.

Intended to help prevent drug side effects and interactions among the elderly, who use 25% of prescribed medications, the ad urges older people to make their physicians aware of medicines they are taking. The ads, which also include spots on exercise and nutrition, are to be distributed through contacts designated by the governor in each state and will include a local tag line identifying organizations where the elderly can obtain further information.

A toll-free hotline to provide information and program assistance to the aged and to health professionals has been established in the HHS Office of Disease Prevention and Health Promotion (1-800-626-5433).

Status Report on Second Surgical Opinion Programs

AMA COUNCIL ON MEDICAL SERVICE

Since 1976, the Council on Medical Service has submitted periodic reports to the House of Delegates on the subject of second surgical opinion programs. These reports identified a number of issues which required long-term study concerning the impact of these programs on the health status of the population involved, and urged that there be no further proliferation of such programs until the experience of those programs then operating, and their impact on quality, appropriateness, accessibility, and cost of care, could be better evaluated.

At the 1982 Annual Meeting, the Council reviewed the status and results of second surgical opinion programs in both the public and private sectors and found no conclusive evidence that these programs had favorably impacted on the quality, appropriateness, accessibility, or cost of care. Particularly needed, in the Council's view, was a better understanding at the clinical level of the long-term physical and psychological effect on patients who elect not to proceed with surgery, and of the cost of alternative nonsurgical treatment for those patients.

Current Association policy on second surgical opinions is expressed in the following two statements:

(a) Third party payers, working with providers, should undertake conscientious evaluation of the methodologies and the results of current experimentation with coverage of second opinions prior to elective surgery. The long-term results and general adaptability of such programs should be evaluated in terms of medical care quality, cost effectiveness, the cost and quality of alternative care provided in place of surgery, and the long-range medical implications for the patients who did not have surgery.

(Recommendation 27 of the National Commission on the Cost of Medical Care; approved by the House of Delegates at the 1978 Annual Meeting.)

(b) Recognizing that the advisability of surgery or other specific therapy can be a matter of opinion, the House of Delegates of the American Medical Association (1) reaffirms the right of a patient or a physician to seek a second opinion freely from any physician of his/her choice; (2) opposes the concept of mandatory second opinions or the imposition of financial penalties by a third party payer for not obtaining a second opinion; and (3) supports the concept that when a second opinion is required by a third party, that second opinion should be at no cost to the patient.

(Council on Medical Service Report J, adopted at the 1978 Interim Meeting. This policy was reaffirmed at the 1982 Annual Meeting of the House of Delegates.)

The purpose of this report is to apprise the House of significant developments in the area of second opinion programs since the Council's June, 1982, report.

Public Sector Activities

The federal government is attempting to study the cost effectiveness of its two-part national second surgical opinion program initiated in 1978 and described in Council on Medical Service Reports J (I-78) and B (A-82). As the House will recall, the Health Care Financing Administration (HCFA) began a program in the fall of 1978 to encourage the seeking of second surgical opinions by the public, particularly Medicare and Medicaid beneficiaries, and to identify, through its regional offices, local organizations such as PSROs, Medicare carriers, or medical societies who would develop and maintain lists of physicians willing to provide such second opinions. (Second opinions were already paid for by Medicare, subject to the normal deductible and coinsurance provisions, even though not specifically identified as such; HCFA's stated intention was to encourage greater use of this benefit.) State Medicaid agencies were also encouraged to pay for such consultations and to refer recipients to the appropriate sources of information on physicians willing to provide the second opinion.

The first stage of HCFA's program was the creation of a nationwide network of 150 sources for referral to second opinion physicians. These referral sources voluntarily developed and maintained lists of physicians willing to give second opinions. The number of physicians nationwide who have agreed to provide second opinions in this program is not known; however, about 40 percent of the referring organizations were medical societies. Despite a nationwide media campaign between 1978 and 1980, an early evaluation by Abt Associates, a research and consulting firm, under contract with HCFA reported that the use of the program averaged only about four requests for the names of second opinion physicians to the referral centers per 100,000 population per year. The Abt study concluded that utilization of the referral centers did not have a measurable effect on national surgery rates over the population as a whole.

The second aspect of HCFA's second surgical opinion activity was an evaluation of two Medicare second opinion demonstration projects and a mandatory second opinion program for Medicaid recipients. The two HCFA-funded Medicare demonstration projects are administered locally by Blue Cross and Blue Shield of Greater New York and Blue Cross and Blue Shield of Michigan. Participation in these programs is voluntary and is limited to Medicare beneficiaries with Part B coverage in 17 counties in New York (including New York City) and in the three-county Detroit metropolitan area. Both programs pay the cost of the second opinion consultation, regardless of the normal deductible and coinsurance status of the beneficiary. The Detroit program offers the additional service of scheduling consultations for its subscribers.

The federal government has contracted for a detailed analysis to determine whether second surgical opinion programs have been effective in reducing the number of elective surgical procedures—non-emergency surgeries that can be postponed or avoided without undue risk to the patient. This review showed that voluntary programs have not had a significant impact on the number of elective surgical procedures performed under both the Medicaid and Medicare programs due, in large part, to the fact that few people seek second opinions voluntarily. On the other hand, the mandatory programs *appear* to be effective in reducing both the volume of elective surgical procedures and the overall costs of surgery, without assessing the costs of the second surgical opinion benefit.

Current Extent of Voluntary Programs

Almost every state Medicaid program and over half of all Blue Shield Plans offer some type of second surgical opinion program, most of which are voluntary. A recent HCFA report to Congress concluded that "the most striking fact regarding all voluntary second surgical opinion programs is that few people choose to use them." For example, in the New York demonstration project, only 1,763 of the 142,000 (1.2 percent) recipients who underwent surgery obtained a second opinion prior to surgery. The utilization rate was even lower in Michigan where only 116 of the 44,000 (0.3 percent) recipients who were operated on obtained second opinions. According to evaluations performed by HCFA and Abt Associates, participation rates nationally in the voluntary programs are very low—about 2 to 5 percent.

The demonstration programs have shown that surgery has been reduced among those who participated by, at best, about 12 percent. If 2 percent of Medicare beneficiaries participate in a structured, voluntary second surgical opinion program, and surgical procedures among these participants decline by 10 to 15 percent, then the overall reduction in total beneficiary surgery is 0.2 to 0.3 percent. HCFA also concedes that confirmations might actually *raise* the likelihood of surgery for participants in the demonstration programs. (Since confirmations outnumber nonconfirmations by more than 2 to 1, the offset of increased surgery could theoretically exceed the reduction from nonconfirmations and yield an increase in the total number of elective surgical procedures performed.) For selected procedures, this conclusion was also reached by Blue Cross and Blue Shield of Greater New York following an evaluation of its own program.

Current Extent of Mandatory Programs

Three state Medicaid agencies with mandatory second surgical opinion programs have reduced elective surgical procedures and associated costs. In these states (Massachusetts, Michigan, and Wisconsin), the programs have focused on up to ten selected surgical procedures that, in the program directors' opinion, had the highest incidence of inappropriate surgery. Physicians are not reimbursed for performing the surgery without a second opinion. The recipients, however, retain their right to make the final decision on whether to have the operation.

In the Massachusetts program, it has found that Medicaid saved $3 to $4 for every dollar spent; cost savings were estimated at more than $1 million per year. Overall surgery was estimated to have dropped by 20 percent in the year after program implementation. The decline in surgery rates was attributed both to a direct effect on patients referred to the program and to a "sentinel effect" whereby fewer operations were proposed.

Surgical utilization in the Michigan program dropped about 35 percent, and the Michigan Department of Social Services estimated annual savings to be about $3.7 million.

The Wisconsin program netted $2.8 million in total savings—$1.8 million in total Medicaid savings and almost $1 million in Medicare savings. The program returned almost $22 in savings for every dollar spent on program costs. Overall surgery was estimated to have dropped by 33 percent as a result of the program. The percentage drop varied by procedure and ranged from 17 percent to 48 percent. Wisconsin, too, attributes much of the drop in surgery to the "sentinel effect."

The savings mentioned above cannot be generalized from such a small sample. These three states are northern states and may not be representative of the nation as a whole in terms of population and health care utilization. In addition, the costs of medical treatment (in lieu of surgery) and possible later surgery appear to be excluded from the figures cited.

Future Directions

In a May, 1983, report by the Inspector General of the Department of Health and Human Services to the Administrator of the Health Care Financing Administration, it was recommended that HCFA seek to legislate a change in the Social Security Act that would require all states to adopt mandatory second surgical opinion programs for the Medicaid and Medicare programs. The Inspector General's report, citing the experience of the Massachusetts, Michigan, and Wisconsin Medicaid programs which indicate that a mandatory program reduces the number of surgical procedures from 20 to 35 percent at a savings of approximately $3.48 for each Medicaid recipient, projected an estimated annual savings in the Medicaid program of as much as $63 million. The Inspector General further believed that a mandatory program would also be effective in Medicare, considering the number of Medicare beneficiaries and the fact that the elderly have surgery performed twice as often as the rest of the population. It was estimated that a mandatory program for just nine surgical procedures (prostate surgery, joint replacement, hernia repair, cataract removal, cholecystectomy, varicose vein excision and ligation, hysterectomy, hemorrhoidectomy, and dilatation and curettage) could save the Medicare program $94.7 million annually.

HCFA disagreed with the Inspector General's recommendation to seek legislative approval for a mandatory second surgical opinion program. It was HCFA's view that, although mandatory programs *appear* to be more cost effective than voluntary programs, experience with these programs has been very limited in public and private sectors alike. HCFA recommended that another three to four years of study be conducted into the long-run effects of mandatory second surgical opinion programs before introducing legislation to mandate the program on a national basis.

HCFA's recommendation not to mandate a second surgical opinion program was based on several factors. HCFA questioned the validity of the data and methodologies used in the Inspector General's report and argued that the report did not contain sufficient analysis to document the estimated cost savings. HCFA's primary concern was the possibility that a mandatory program could have a negative impact on health status through the deferral of needed surgery. Concerns were also expressed regarding beneficiary freedom of choice and the potential liability of the surgeon and/or hospital.

The Council believes that HCFA's reluctance to endorse mandatory second opinions is well-founded, and that its position on this subject is reasoned and in the best interests of Medicare and Medicaid beneficiaries. In view of the important questions that remain unanswered, HCFA is conducting its own examination of the mandatory programs that have been implemented in both the public and private sectors. HCFA has met with several insurers and states to learn more about their experience and administrative problems with mandatory programs. In addition, HCFA is awaiting the final results of the Abt Associates report of the voluntary Medicare program in New York and the mandatory Medicaid program in Massachusetts. This report, which was scheduled to have been completed in the fall of 1983, is now projected to be completed during the summer of 1984.

The AMA has communicated with the project officers at both Abt Associates and HCFA regarding the forthcoming report. The results in the final report are not expected to deviate substantially from those in preliminary reports, the findings of which are reported above. It has been concluded that second surgical opinions are a valuable addition to the national health care scene and that their use should be maximized. According to preliminary findings by Abt Associates, voluntary programs do not significantly increase the use of second opinions and direct savings are very low. However, mandatory programs appear likely to save close to $100 million per year, with much of the savings attributed to the so-called "sentinel effect." The final Abt report will thus focus on the mandatory option as a means of effecting the largest amount of savings.

Private Sector Activities

The Blue Cross and Blue Shield Association has encouraged its member plans to develop second surgical opinion programs. Currently, 59 plans offer programs to at least a portion of their subscribers, and these programs vary in size and scope. Of these 59 plans, 16 offer mandatory programs in addition to their voluntary programs. To assist subscribers in seeking a second opinion, 35 plans operate referral centers.

Blue Cross and Blue Shield plans have experienced nonconfirmation rates ranging from 50 percent to 25 percent in their voluntary programs. Utilization of benefits in voluntary programs has been very low. The number of plans offering mandatory programs and the number of subscribers covered are growing rapidly, but most of the mandatory programs are too new to have meaningful data as yet.

The Health Insurance Association of America (HIAA) also encourages its member companies to consider second opinion programs as a possible cost-effectiveness measure. HIAA does not recommend either a voluntary or a mandatory program, in the belief that this should be left to the option of the member company and/or the policyholder. A 1982 HIAA survey of 4,268 new or amended group health insurance contracts found that about three-fourths of the new contracts (76 percent) provided coverage for second opinions prior to nonemergency surgery. Only a small number of these mandated the second opinion as a prerequisite for reimbursement for the surgery.

Metropolitan Life Insurance Company offers its group accounts both voluntary and mandatory, or "incentive," second surgical opinion programs. Both programs reimburse second (and third, if necessary) surgical opinion consultations rendered by board-certified specialists for elective, nonemergency procedures at 100% of the reasonable and customary level. Any necessary tests and x-rays are also reimbursed in full. The mandatory programs single out a selected list of surgical procedures for which a second opinion is required in order to obtain full reimbursement. Metropolitan is currently developing an improved electronic reporting system that will produce composite experience on all group accounts with second surgical opinion programs. This system is expected to form a broad data base to analyze nonconfirmation rates by specialty and procedure. Additionally, the company has developed a nationwide panel of board-certified physicians who are available to perform second opinion consultations for group customers.

Metropolitan reports that participation in voluntary programs has been low, usually less than 2 percent of eligible beneficiaries. Notwithstanding the low utilization rate, the nonconfirmation rates for those patients who do obtain a second opinion range from 25 to 35 percent. Reported net savings for several group accounts with a combined employee population of 30,000 and a voluntary program in effect for at least four years exceeded $1 million as of 1982. Metropolitan%s experience during the last two to three years with mandatory programs of several large accounts resulted in increased numbers of participants. Early experience with the mandatory program has indicated a 3 to 5 percent nonconfirmation rate.

Prudential also offers two separate second surgical opinion program options. Under the voluntary option, surgical benefits are payable for surgery performed without regard to the patient%s seeking a second opinion or securing confirmation of the need for surgery. The "incentive" option provides for a lesser surgical benefit for elective surgery in the absence of a confirming opinion. Prudential maintains a nationwide network of nearly 20,000 board-certified specialists who have agreed to provide second and, if necessary, third opinions to employees of its group accounts. Prudential arranges the appointment with the specialist chosen by the patient and conducts the necessary follow through. There are 114 nonemergency elective procedures that fall under the voluntary and incentive options.

Prudential has compiled combined first and second quarter 1983 company-wide statistics on both the voluntary and incentive options:

Voluntary Plans

Estimated net savings: $ 194,100
Estimated net savings per consultation: $ 966
Consultations performed: 201
Confirmation rate: 84%
Utilization rate (consultations): 6 per 10,000 lives

"Incentive" Plans

Estimated net savings: $1,911,610
Estimated net savings per consultation: $ 605
Consultations performed: 3,162
Confirmation rate: 90%
Utilization rate (consultations): 96 per 10,000 lives

The longest running second surgical opinion program studies were initiated in 1972 at Cornell-New York Hospital. The study group was drawn from 743,000 individuals covered by several Taft-Hartley health and welfare funds in the New York City area. Over an eight-year period, 12,000 persons received second opinions. Among this group, approximately 33 percent in a voluntary program and 18 percent in a mandatory program were not confirmed for surgery. Taking into account the savings in health care expenditures and reduction in days lost from work, total savings in the program were estimated to be about $535,000 ($362,000 less on medical care and $173,000 for productivity not lost). The estimated cost/benefit ratio of savings to program costs was $2.63 for each dollar spent on the program.

There have been conflicting reports on the effectiveness of second surgical opinion programs in reducing the increase in medical care costs. While many insurers have instituted formal second surgical opinion programs, few have recorded their experiences. In view of the limited experience with and sparcity of data on these programs, the Council feels it is premature to encourage the proliferation of mandatory programs without further evaluation and analysis.

Despite low utilization of the voluntary programs, savings have been achieved while, at the same time, patient freedom of choice has been maintained. Mandatory programs do appear to save money in the short term, but further evaluation is necessary to determine their impact on long-term aggregate costs. Still needed, as stated by the Council in previous reports, is a better assessment of the long-term physicial and psychological effect on patients who elect not to proceed with surgery, and of the costs of alternative nonsurgical treatment for those patients. In addition, the cost to administer such programs is quite high, and any savings achieved may ultimately be negated by the cost of the program (informing patients of the second opinion option, the actual cost of the second and possibly third opinions themselves, arranging for second opinion consultations, and follow-up and care of those patients who do not have surgery).

In conclusion, based on its ongoing review of the results of second surgical opinion programs, both voluntary and mandatory, the Council on Medical Service continues to believe that conclusive evidence is not yet available on the overall impact of these programs on the quality, appropriateness, accessibility, and cost of care. Accordingly, the Council believes that present Association policy on this subject continues to be appropriate. The Council will continue to monitor the results of second surgical opinion programs in both the public and private sectors and will inform the House of Delegates of these results as appropriate. The Council will also attempt to evaluate the results of the many other approaches to constraining health care costs currently being applied or explored, with particular attention to the impacts on quality and accessibility as well as costs of care. The findings of such evaluations will be conveyed to the House of Delegates.

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Editorials

A Who's Who of Litigants: A Powerful Resource in the Malpractice Crisis.

The AMA, Connecticut State Medical Society and ConnTORTs press for legislative measures to correct an intolerable medical liability system. Such proposals face fierce opponents in trial attorneys who find nothing wrong with the present system and who are well entrenched in legislatures. A conflict of interest here is evident and a revamping of the system by medical organizations will be entangled in difficulties.

American trial lawyers constitute a small but powerful segment of the legal profession. They recently aroused international disdain when scores of them descended on India to sign up victims of the Bhopal disaster. During that unseemly scramble for litigants, one attorney reinforced the image of venality by stating, "Our motivation is to make money from the disaster—make no mistake about it." When the Indian government itself reacted to such ambulance chasing, a group of American attorneys announced plans to sue the Indian government for loss of income, talking of "normal damage suit fees of 33%." An associate of Melvin Belli stated, "It could be the largest recovery for U.S. attorneys in the history of the American legal system." Given such attitudes, it would be self-deceptive for medical organizations to expect trial lawyers to be fair and reasonable in establishing an equitable medical liability system.

Aside from the more obvious faults of the present tort system, there is something else that is radically unjust. What may appear as "malpractice" incidents, or maloccurrences, happen many times more often than the number of law suits indicate. Most patients do not seek redress in the courts, perhaps because they recognize medicine as the imperfect science it is. Armed with hindsight, there is no end of evidence that, even among the best of physicians, fallibility and imperfection prevail. If every misdiagnosis or medical mishap were compensable at present levels, the sums needed would exceed the federal budget. The present system allows for gross overcompensation of the relatively few litigious (and their attorneys), while other patients are footing the bill.

Considering the slowness and long struggle for legislative change, there is one step, however, that can be implemented legally and without much delay. We can make available to all practitioners a list of medical malpractice litigants in their region, perhaps computerized at the county or state level. Along with the names of claimants would be listed the names of their attorneys. Names of physicians would be omitted because, in the majority of cases, they are ultimately proven innocent of malpractice.

Once a suit is filed in court, the information pertaining to that case is in the public domain and releasing it does not violate medical confidentiality. One purpose of the listing would be to enable practitioners to study, from court records, cases of special interest in order to prevent repetition of errors.

Another purpose would be to provide for the litigious the best medical care available, strictly following with them the advice usually given by attorneys on "how to practice court-oriented medicine"—and on judicially correct doctor-patient relationship.

Though we know this type of practice to be costly in time, effort and money, it is considered by the legal profession to be part and parcel of good medical care (e.g.: no phone advice, abundant use of consultations and tests, non-trust in clinical experience, judgment, or lab results without repeating them, practicing and advising in the presence of witnesses, recording all minute details, etc.). Even medical and surgical developments and adverse effects that are only remotely possible should, in such medical practice, be described in detail; and conversations about them should be documented and signed. Frequent follow-up visits must be recommended to check for marginally-possible developments, and in the case of

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broken appointments, registered letters should be sent advising of the danger of missing an advised consultation or a re-examination. All possible side effects of drugs, even those rarely encountered, should be described to such patients in the presence of a nurse or other witness.

Ultimately, some relief in the malpractice crisis might possibly come from the legislature. But don't let's hold our breath. In the meantime, in dealing with litigation-prone patients, it becomes necessary to put in practice a combination of excellent medicine with emphasis on "preventive jurisprudence." To know which patients should be so treated, area lists of litigants can provide an answer.

Hans H. Neumann, M.D.

Wilton, CT

The MRI Scanner and What We Don't Learn from History

The MRI (magnetic resonance imaging) scanner is a new, expensive diagnostic tool capable of giving information that is otherwise unobtainable by any other non-invasive technique. It is particularly useful in demonstrating lesions in the brain stem and cervical spinal cord and thus is of great interest to neurosurgeons and neurologists.

The instrument was developed in the United Kingdom and is now manufactured by a number of companies including General Electric. MRI scanners are costly. All but the very low gauss machines (which are not favored in the USA because of relatively inferior resolution) require a special room with shielding to protect against the powerful magnetic field generated. Typical cost of purchase and installation at the present runs between two and three million dollars. There is also an estimated annual operating cost of about $900,000.

Because of the expense involved with MRI scanning, there have been a number of groups, some self-appointed, some public, others private trying to decide how many scanners are needed in the state of Connecticut and where they should be located. A similar phenomenon occurred over a decade ago with the advent of the EMI model of the CT head scanner. By and large, the "cost control groups" did nothing more than impede the logical and inevitable installation of the CT head scanner in every hospital in the state with a major neurosurgical service. It now would be considered impossible for a hospital to have a neurosurgical service without a CT scanner. How many patients may have died or been maimed for want of a CT scanner in the 70's will never be known but there is no question that the tardy installation of the scanners was directly due to the well meaning but obstructionistic tactics of various cost control groups. We are now witnessing a similar problem with the MRI scanner. To paraphrase Hegel (1832), "What history teaches us is that people have never learned from history."

There is now a Connecticut task force of radiologists and laymen working on phase two of a plan for allocating MRI scanners in the state. Distribution probably will be based upon the number of CT scans now being done in various institutions. There is no consideration being given to the size of the neurology or neurosurgical services in the hospitals involved. Phase one of the study has already concluded that MRI scanners should be approved for Yale-New Haven Medical Center, the second largest hospital in the state, and the John Dempsey Hospital. The Dempsey Hospital qualified in spite of its small size because it is engaged in research and teaching. This is curious reasoning because the MRI scanner is an instrument designed primarily for clinical diagnosis, not for research. In addition, Hartford, the largest hospital in the state with the largest neurosurgical service is involved in teaching and research as is Saint Francis, also one of the busiest hospitals in Connecticut.

One self-appointed group struggling with the question of how many MRI scanners are needed in the Hartford region and where they should be located is the Capitol Area Health Consortium. In the Newsletter of the Consortium, May, 1985, we are told that the Consortium Committee on Magnetic Resonance Imaging, consisting of nine members, none of whom is a radiologist, neurosurgeon or neurologist, has approved a policy that there shall be only two MRI scanners in the area, one of them to be located at the John Dempsey Hospital. The second scanner is to be freestanding and to be owned and operated by the Consortium. This would leave Hartford Hospital and Saint Francis Hospital, the hospitals with the two largest neurosurgical services in the area with no *in situ* MRI scanner. Immediately brought to mind is the picture of a desperately ill post-operative patient on an Ambu bag respirator being put into an ambulance and carted across town to an isolated MRI unit so that it could be determined whether blood clot or swelling of the upper cervical spinal cord was present. In one case (clot) emergency re-operation would be indicated, in the other (swelling) surgery would be meddlesome—the MRI could tell. Many other potentially disastrous situations are possible.

The Consortium now has decided to spend $100,000 to hire Robert Douglass Associates, a Texas consulting firm, to help prepare a certificate of need. One does not have to spend $100,000 to determine the obvious. Any hospital with a major neurosurgical service must have a MRI scanner. To plan otherwise is merely to postpone the inevitable and meanwhile jeopardize patient care. Hegel was right.

Melville P. Roberts, M.D.

William Beecher Scoville Professor of Neurosurgery,
University of Connecticut School of Medicine;
Senior Attending Staff,
Department of Neurosurgery, Hartford Hospital

Joseph S. Sadowski, M.D.

Senior Attending Neurosurgeon, Saint Francis Hospital;
Past President, Connecticut State Medical Society

The Favorable Prognosis

As a psychiatrist, I have found it wise to offer a favorable prognosis to the great majority of my patients.

Despite a great number of prospective and retrospective studies, little is known about prognosis in any individual instance, and we too often tend to extrapolate, with no scientific basis, the past into the future. Most individuals with emotional disorders recover spontaneously, due to changes in environment, encouragement and support from friends and relatives, and other factors we cannot determine. With or without therapy, for instance, the seriously acting-out adolescent frequently becomes the mature stable adult, while the depressed person tends to "snap out of it."

The psychiatrist has available a wide range of tools: in addition to various conventional psychotherapies, many other effective methods have been introduced through the years, such as time-limited, goal-limited, group and family therapy, and behavioral modification, to name but a few. Treatment has been revolutionized with the use of tranquillizers, anti-psychotic, anti-depressive and anti-manic agents, and potentially more effective chemicals are in the wings. There is intense and productive research in these fields. Thus, because of the likelihood of natural remission and the psychiatrist's increasingly useful armamentarium, the emotionally disturbed patient now stands a better chance of recovery than ever before.

A favorable prognosis can emphasize the positive, offer hope, and set in motion a self-fulfilling prophecy. In the course of mental disorder, neurotic symptoms come to the forefront, and intrinsic abilities and assets tend to be submerged. The disturbed person may be withdrawn, belligerent, ungrateful, indiscreet. He often engenders antangonism, fear, frustration and distancing in his environment, which in turn can reinforce his apathy and feelings of worthlessness and helplessness. Family and friends may adopt negative attitudes towards the patient and his future. The psychiatrist, trained to elicit and emphasize defenses and deficits, may tend to lend less significance to his patient's latent assets. A vicious circle may be created when the psychiatrist informs the family that the outlook is gloomy. The stating of a poor prognosis, however presented with intelligence, tact and thoroughness, may introduce further confusion and hopelessness in an already discouraging environment.

In order to introduce a more optimistic approach, the therapist may say to a relative, "As bad as things appear now, there are not only psychotherapy and medications to help, but there are also spontaneous tendencies toward recovery. The next few months may be difficult for the patient and for yourselves. The patient requires all the help he can get from us all, and yours will be vital and ultimately productive." One can frankly solicit and discuss the family's feelings about the patient, whether these be helplessness, guilt, anger, and make suggestions to alleviate suffering and help reduce tension within the family. This positive reinforcement can foster optimism and in turn offer the patient a more hopeful outlook and inducement to improve.

One can make a matter-of-fact statement to the patient, that he can and will be better, buttressed by warmth and support and the powerful encouragement inherent in concern and dependability. Along with *nolo non nocere,* "Accentuate the Positive," in the words of the popular song, are most important creeds in psychotherapy, and can offer a suitable medium in which recovery can take place.

The therapist himself may benefit from his optimistic prediction, and become that much more committed to suiting his performance to his prophecy.

If the favorable prognosis is not realized, the psychiatrist, family and patient can at least recognize that everything possible has been done to help, and this can act to reduce centrifugal forces within the family, so common when a member is emotionally disturbed.

The therapist must take the long and broad view. Since the majority of individuals with emotional disorders improve, given time, it is his responsibility to influence, to the best of his ability, the patient's psychobiological mechanisms and the external environment, so that nature's homeostatic forces can better exploit his underlying resources.

Paul E. Kaunitz, M.D.
Clinical Professor of Psychiatry,
Yale University School of Medicine

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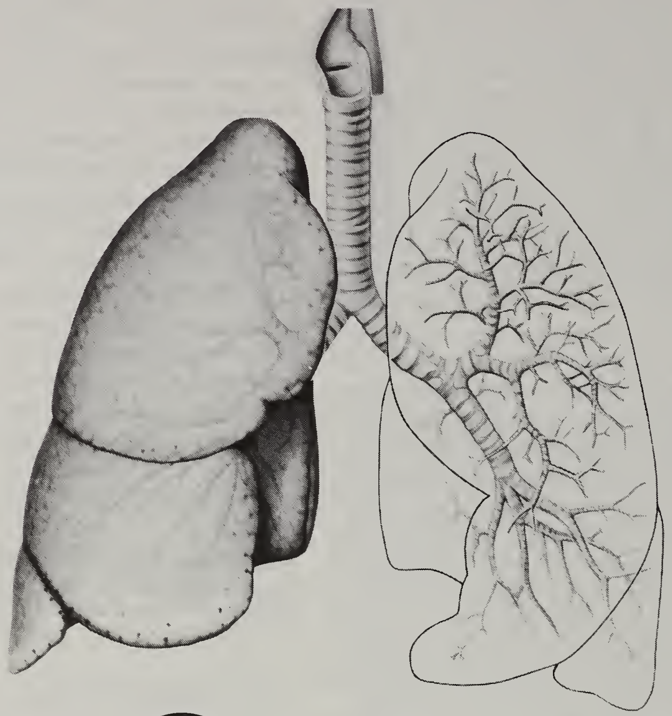

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Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C difficile* Other causes of colitis should be ruled out

Precautions: *General Precautions* – If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e g , pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms Careful observation of the patient is essential If superinfection occurs during therapy appropriate measures should be taken

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug

Ceclor should be administered with caution in the presence of markedly impaired renal function Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly)

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis

Usage in Pregnancy – Pregnancy Category B – Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers – Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively Trace amounts were detected at one hour. The effect on nursing infants is not known Caution should be exercised when Ceclor is administered to a nursing woman

Usage in Children – Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain – Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic – Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic – Transient fluctuations in leukocyte count predominantly lymphocytosis occurring in infants and young children (1 in 40)

Renal – Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200)

[061782R]

Note. Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information

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The President's Page

The Journey of a Thousand Miles

The current system of tort litigation is producing a progressively adverse emotional impact on the medical profession. Furthermore, it is partially responsible for increases in the cost of medical care as physicians continue to practice defensive medicine, the estimated cost of which may be 15-40 billion dollars per year. Finally, and most tragically, in order to defend themselves, physicians are beginning to limit their medical and surgical services, thus reducing the availability of vital and perhaps life saving care to those in need. The last reaction is by far the most serious consequence!

The emotional cost to a physician once he or she is named as a defendant in a professional liability suit has been studied and addressed in a survey of Chicago area physicians by Sarah Childs, M.D. Dr. Childs reports that physicians when sued experience "anger, indecisiveness, inability to concentrate, and lose courage." It is further reported that the emotional strain can give rise to anxiety and symptoms such as "insomnia, depressed mood, loss of energy, somatic complaints, lack of concentration, irritability, and loss of confidence." Consider the effects of these reactions on family relations. Consider the influence on the practice of defensive medicine. Finally, and most important, consider the potential effects on the quality of care of future patients.

Current trends indicate that remedial legislation is increasing on a statewide basis. Five states have adopted a medical liability tort reform package. The most recent successes have occurred in Illinois and Florida. Legislation is pending in at least thirty states to reform medical liability laws. In our state of Connecticut, the Connecticut State Medical Society was instrumental during this past year in passing a collateral source law while protecting our statute of limitations. In California, the Medical Injury Compensation Reform Act (MICRA) of 1975 has survived two legislative challenges.

On a national level, the AMA is supporting the concept of substantial incentives to states to pass and retain key tort reform legislation. In congress, this concept is being supported by Robert Mrazek (D-NY) and others who have introduced bills proposing federal incentives to states that adopt certain medical liability reform.

Simultaneously, dialogue in the press and other media is beginning to place the problem of medical malpractice in proper perspective in stating that "simplicity in medicine has given way to legal complexities," and that in the final analysis, "society cannot hold doctors to unrealistic standards of perfection."

It is an incorrect assumption that the malpractice problem will be solved by passing an ideal complete tort reform package. It is estimated that tort reform will control only 20% of the problem. Of equal importance, is the implementation of a risk management program which is designed to prevent and avoid negligence, accidents, and maloccurrence. With our establishment of the Connecticut Medical Insurance Company, we have the opportunity to establish a coordinated effort to achieve significant control of the malpractice problem. This will require, however, unity of purpose by all of the state physicians supporting the actions and activities of the Connecticut State Medical Society and the Connecticut Medical Insurance Company.

"The journey of a thousand miles always requires the first step." We have taken two steps in the last two years by energizing CMIC and by achieving the passage of the Collateral Source Law. Everyone reading this homily should be a member of CMIC while remaining informed and in support of the activities of our Legislative Committee. What other alternatives do we have?

William A. Whalen, M.D.,
President

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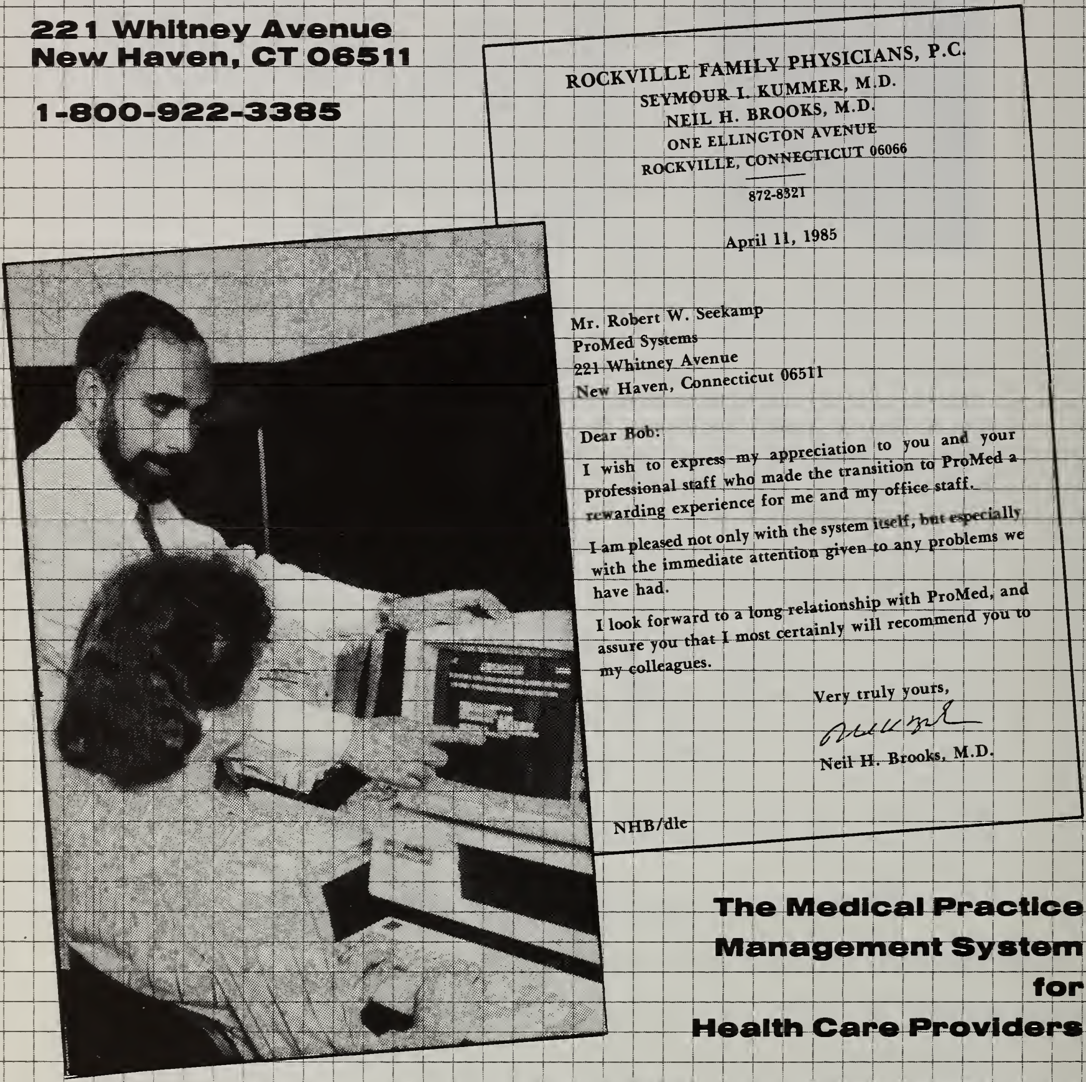

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Reflections on Medicine

Rights and Obligations

ROBERT U. MASSEY, M.D.

Several months ago I wrote about our need to develop a health policy, one suited to our ideals, and one in the fashioning of which patients, doctors, and other health professionals would take the lead. I expressed a serious concern that profitability in one way or another was coming to have the upper hand in deciding our course. When resources appear to be limited it is easy enough to understand why managers should pay special attention to the "bottom line."

Policy, however, if it is to work, must express the public philosophy even though that may be poorly defined, as it often is, in a democracy such as ours where the conflict between rights and obligations has never been entirely resolved. When the public philosophy is at odds with itself, how can a coherent policy be drawn from it? We have come in the past two decades to consider medical care a right, or at least we have agreed that no one may be denied care because of lack of money to pay for it. Having affirmed that in thousands of separate decisions, we are alarmed at the cost, and have turned first to the regulators and then to the market for discipline.

Experience has shown that the market is an effective control upon prices and then upon costs; the closer to the ideal market, the better it works. Medical care, because of insurance and government support, no longer shows many of the characteristics of the ideal market; hence costs have been weakly restrained, and the apparent solution is to impose market forces. Not all would agree with the soundness of this proposal; even economists might dispute both the simple assumption and the even simpler conclusion.

But may we consider imposing market forces upon the distribution of a service which we have just agreed is a right? Markets apply to shoes and ships and sealing wax, to automobiles and vacation travel and computers; markets do not apply to things that are rights. The market stopped applying to the schooling of children between the ages of six and sixteen once we became clear about the right to public education. Of course public schools have never been everywhere equal in accessibility and quality, and in that sense some larger market has operated; but our policy has always been to take steps to correct that inequality within our willingness to pay. This matter of rights may need re-thinking in the light of its consequences.

The provision of public education did not preclude the parallel rise of private schools which obeyed market forces. The assurance of first-rate medical care available to everyone would not preclude the parallel rise of new systems of care for those with the means and the inclination to pay for more. Private hospital rooms with television, face-lifting plastic surgery, semi-annual physical examinations—everyone has his list of frills—may be provided by the market for those with special needs and means. But if we have singled-out medical care to be a right then it follows that it should be available to everyone. It is a contradiction to assert that something is a right and then subject it to market forces.

There are analogies to be found in the history of the development of public schools in this country; these analogies are probably more comfortable for us to follow as we struggle with the notions of health policy than those drawn from the examination of health services in other countries.

Public education and public health developed generally in a parellel fashion in America and Western Europe. In both the aristocratic governments and in the evolving democracies it was becoming clear that a healthy and literate populace could best serve their own needs and the needs of the state. John Stuart Mill wrote that "no form or combination of social polity has yet been devised to make an energetic people out of a community of citizens personally feeble and pusillanimous." Both physical and intellectual strength are implied, and public health has come to encompass essential medical care.

There is a risk in making too much of perceived analogies. A medical care system based upon towns, cities, and counties, for example, might be unworkable; any government system, local, statewide, or national, may be unacceptable. Yet when we have declared a right without setting limits, we have possibly assumed an obligation without counting the costs; we may nevertheless have to adapt to the consequences.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Decisions at the End of Life: The Legacy of Karen Ann Quinlan

JOSEPH M. HEALEY, J.D.

The development of an appropriate public policy concerning care and levels of support for the dying patient is a formidable task which continues to trouble us in 1985. There are constant reminders of the complex issues involved and of the absence of consensus in our society about what the policy ought to be. This past June, Karen Ann Quinlan died after spending more than ten years in a persistent vegetative state. Earlier this year, the New Jersey Supreme Court became the first state court of highest jurisdiction to consider whether it is ethically and legally permissible to withhold or to withdraw artificial feeding from an incompetent patient. In June, the Connecticut legislature approved "living will" legislation after rejecting similar proposals for the past several years. These three events reflect the progress which has been made in clarifying the rights and duties of patients, health practitioners and family members. They also represent the problems which remain and must be confronted. My next three columns will explore these three events and their implications for the future development of policy.

The *Quinlan* case[1] is the starting point of almost every discussion dealing with care of the dying patient. Karen Quinlan was a 21-year-old brought to the emergency room of a New Jersey hospital experiencing respiratory distress secondary to an insult of unknown etiology to her central nervous system. She ceased breathing for two fifteen-minute periods but was resuscitated once by her friends and once by the police. Upon her arrival at the hospital, she was placed on a respirator and the search for the cause of her respiratory difficulties and for a strategy to manage them began. During the next few months, over 300 tests were performed, none of which revealed the precise nature of her lesion. Her condition did not improve. It was believed that she was in a persistent vegetative state with no apparent reasonable likelihood of returning to her previous level of functioning. After a period of considerable anguish and soul-searching, her parents concluded that the respirator was prolonging her death rather than enhancing her life. They requested removal of the respirator. The doctors refused to comply with the request of the Quinlans, who subsequently filed suit. There were two levels of court review. The trial court, the New Jersey Superior Court, denied the major portions of relief sought by the parents concluding that neither the civil law nor the criminal law supported removal of the respirator. On appeal, the New Jersey Supreme Court overruled, holding that the patient's right of privacy may, in certain circumstance, serve as the basis for the refusal of treatment, that such rights may be exercised for an incompetent adult by a surrogate, and that to eliminate potential civil or criminal liability, such decisions were to be made by the surrogate and the responsible physician in consultation with an institutional "ethics committee." Though the respirator was removed in the spring of 1976, she survived in a New Jersey nursing home until her death in June, 1985.

Perhaps the greatest legacy of the *Quinlan* case is its affirmation of the principle that incompetent adults do not lose their right to self-determination because of their incompetence. Rather, the primary question involves developing an acceptable process through which a surrogate can be identified and the rights of the patient can be given voice. The process described in the *Quinlan* case has been criticized for its concern with reducing or eliminating liability for the physician rather than with implementing the patient's wishes. Nonetheless the *Quinlan* case represents a dramatic step forward by dealing with issues of life and death publicly in ways which attracted the attention and involvement of society. As such, the case marks the beginning of a fruitful period in medical law during which the boundaries of rights and duties have become clearer. The *Quinlan* case did not deal directly with all the major substantive issues. It did not discuss whether other forms of technological intervention (especially artificial feeding) are to be treated legally in the same manner as the respirator and the ventilator. It did not discuss in detail the use of advanced directives to assist surrogates seeking to implement the wishes of the incompetent patient. Nonetheless, Karen Ann Quinlan became a symbol of the two-edged sword of medical technology and the New Jersey Supreme Court's decision represented the first step in a long process toward clarifying how technology can be harnessed to serve the best interests of patients.

REFERENCE

1. In re Quinlan, 70 NJ 10 (1976).

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Council Meeting

Thursday, June 13, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Beck, Bobruff, Bonner, Canzonetti, Czarsty, Dardick, Freedman, Friedberg, James, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Robbins, Sadowski, Scheer, Sweet, Villa, Waldron, Welch and Whalen, Jr.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Dr. Fabro, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA) and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Kaess, Reyelt, Jr., Rose, Schwartz, Seide, Sullivan, Jr., Zanker and Zlotsky.

Organizational Meeting

The organizational meeting of the Council for 1985-86 was called to order by the President, William A. Whalen, Jr., M.D. Following some opening remarks and the introduction of Council members, elections of a Chairman and Vice-Chairman of the Council for 1985-86 were held. Those elected: Chairman—Guy W. Van Syckle, M.D., Danbury; Vice-Chairman—Mehdi S. Eslami, M.D., Waterbury.

Reports from Physicians Serving on State and Federal Agencies

Dr. Eslami summarized the activities of the Statewide Health Coordinating Council at its May meeting, drawing particular attention to the resignation of Susan Addiss, Bureau Chief, and Task Forces on Magnetic Resonance Imaging and Ambulatory Surgery.

Dr. Eslami detailed the methodology utilized by the MRI Task Force and noted that the group is engaged in developing the criteria for Phase II—Diffusion. He also commented on the workings of the Ambulatory Surgery Task Force and indicated that the report should be completed and available this year.

Dr. Whalen, President of the Connecticut Peer Review Organization, reviewed CPRO activities including the issue of confidentiality of data and the signing of contracts with hospitals to review Medicare cases. He mentioned that CPRO had also signed its first contract for private review with United Technologies and that additional requests for private review had been received. Staff report on CSMS Monitoring of Planning and Regulatory Agencies was received as information.

It was VOTED to go on record with each Connecticut legislator in Congress expressing the Society's concern with the method of "social" admissions to and discharges from hospitals and that discussions be held with the Commissioner of Health to provide for transitional beds in hospitals. It was also VOTED to notify the HSA's, SHHC, AARP and the press of this action.

Report of the President

a) Dr. Whalen reported to the Council on plans to hold a meeting with county presidents for the purpose of planning for a leadership conference and to discuss some of the problems facing the medical profession such as malpractice, HMO's IPA's, PPO's, legislation, medicine's public image, membership, professional unity, Compac, CPRO, CMIC, and communications.

He also reported on the proposed Leadership Conference for the first week in September, which is planned along the lines of the AMA Leadership Conference. Invitations to this conference are to be extended to county officers and individuals who county officers feel are potential leaders of the future. An AMA speaker will be invited to address the conference.

b) Dr. Whalen briefed the members by stating that within the past month the Commission on Hospitals and Health Care (CHHC) had published regulations on the operation of the all-payor legislation and that they have been approved by the Legislature's Regulations Review Committee. These regulations provide for the creation of a central registry for physician codes, requiring hospitals to submit a list of initials, birthdates, and code numbers for all physicians with staff privileges. One of the CHHC's intentions is to require hospitals to link codes with individual patient medical record data. From this linkage, the CHHC will be able to track the hospital practice patterns of all the physicians in the state and further, to be able to conduct individual studies by hospitals and individual physician.

Dr. Whalen went on to state that after consultation between staff, legal counsel and the Officers of the Society, it was agreed that a "Petition for Stay" and a Petition for a Declaratory Ruling" should be sought based on the fact that the CHHC had no right and did not need this data to implement the all-payor prospective payment system in Connecticut. Toward that objective, Dr. Whalen introduced the Society's legal counsels Linda Randell and Jeanette Schreiber, of Wiggin and Dana, who were present to provide members with an in-depth analysis of the two draft documents; "Petition For Stay of Commission Regulations and Filing Requirements," and "Petition For Declaratory Ruling Pursuant To Section 4-176 of The Connecticut General Statutes." Following review and discussion of the documents it was VOTED to support legal action in cooperation with the other named plaintiffs to stay the data collection initiatives of the CHHC and to petition the Commission to declare its initiative illegal or continue the action in the courts. It was also VOTED to have a press release on the matter prepared by staff, CSMS leadership, and legal counsel.

Report of the Executive Director

Mr. Norbeck reported on several items:

a) *AMA Sponsored Teleconference on Professional Liability—6/3/85*

A two-hour AMA teleconference on the professional liability crisis was beamed by satellite to 357 hospital sites in 37 states. CSMS participated through arrangements with the Yale University School of Medicine. Participants were James H. Sammons, M.D., AMA Executive Vice-President, James S. Todd, M.D., AMA Senior Deputy Executive Vice-President and representatives from the American Trial Lawyers, state medical societies and insurance industry. The AMA Task Force on Professional Liability and Insurance has developed a 17-point action plan calling for a public education campaign, legislative reform to cut waste and unfairness from the legal system, coordinated defenses of claims and risk control and quality review to prevent adverse medical outcomes. In the meantime, Dr. Sammons urged individual physicians to improve communications with their patients. Developing and maintaining solid physician/patient relations is one of the best protections against professional liability lawsuits.

b) *American Association of Retired Persons (AARP)*

Mr. Norbeck reported that during the past month he had the opportunity to address another 400 AARP members and the message remained clear—that many do not understand the issues and many do not support prospective payment and DRG's, although their parent organization says that they do.

c) *Legislation*

The results of the legislative activities were highlighted as follows:

Despite massive efforts to block the collateral source bill, CSMS did prevail, and the bill was passed by the General Assembly and awaits Governor O'Neill's signature.

The Statute of Limitation was successfully defended and CSMS also obtained the passage of a bill calling for a study committee for professional liability.

The Seatbelt Law and Living Will legislation, supported by CSMS, also were passed by the legislation.

There were other measures in which CSMS played a part in either supporting or opposing, but defending the statute of limitations and winning the collateral source legislation were the most significant for CSMS. All of the successes were due to a cooperative effort of the CSMS and county medical associations.

Jerome Bobruff, M.D., Chairman of the CSMS Committee on Legislation, further explained that the Legislative Committee, at its first meeting, established a three-pronged goal: (1) To defend Connecticut's favorable statute of limitations law from the expected attacks; (2) To try to gain any degree of tort reform; (3) To support a number of general bills (e.g., Seat Belts, Raising the Drinking Age, Uniform Closing Hours, Living Will, etc.). He reported that the program was successful since CSMS defended the statute of limitations, won on the collateral source and study bills and prevailed on almost all of the bills dealing with the public welfare.

It was VOTED to receive Mr. Norbeck's report and Dr. Bobruff's comments as information and that CSMS send information to its membership explaining its victories in tort reform, etc., and request individual members to send to the Council any suggestions they may have to direct to the newly established State Study Committee on Professional Liability.

Review of Council Subcommittees and Ad Hoc Committees for 1985-1986

Subject committees were reviewed and revisions made as necessary. Attached to these minutes is a corrected copy of these appointments for 1985-86. Two committees were discontinued: The Ad Hoc Committee on Medicare and The Ad Hoc Committee Studying Physician Reimbursement for In-Hospital Care of Patients, Prospective Pricing Systems, Fee Schedules for Physicians, and All-Payors Legislation.

CSMS Ad Hoc Committee on Medicare

Joseph Czarsty, M.D., Chairman of the subject committee, reported on the committee's meeting with Connecticut General and commented on a letter sent to the CSMS President by Charles Polivy, M.D., Medical Consultant for Medicare. The Ad Hoc Committee was formed at the request of Connecticut General and it was believed that it would act as a liaison committee. Following the first meeting, it was determined that the Ad Hoc Committee would not have any opportunity for input into the program and that this committee would be a conduit to convey information and education to the physicians of Connecticut, which was not the original intent for form-the committee. Lengthy discussion followed concerning the various Medicare regulations, and it was finally VOTED that CSMS contact the Connecticut federal legislators and the American Association of Retired Persons, making them aware of the policy of reimbursement for nursing home visits and the problem of conflict between state regulations and federal law concerning the timing and necessity of making nursing home visits. It was further VOTED to seek legal counsel in an effort to remedy the conflict. It was also VOTED that the Ad Hoc Committee on Medicare be discontinued and that a letter be sent to Dr. Polivy informing him that since the committee could not have any input into the program, and that since Connecticut General communicated directly with physicians concerning Medicare regulations, there would not be any need for the committee to act as a conduit.

Health Policy Agenda Advisory Committee Meeting

Stewart Petrie, M.D., representative to the subject meeting, submitted a comprehensive report on the last meeting covering such items as Medical Science, Education, Health Resources, Delivery Mechanisms and Processes, Evaluation Assessment and Control, and Payment for Service. It was VOTED to receive the report as information and to arrange to show a slide presentation on the work of the committee prior to the start of the next Council meeting.

Health Department Procedures Re M.D. License Renewal

A letter was received from a physician member relating to problems he encountered while renewing his license. His license had lapsed for several years before he became aware of it. Because the license had been void more than one year, the Connecticut Medical Examining Board had to act on the reinstatement, causing a delay in the renewal and resulting in great inconvenience to the physician. The CSMS staff researched the issue and found that the department now sends out reminder notices a month before a license is to lapse. This was not being done at the time the incident in question occurred. It was VOTED to accept this report as information.

Appointment of a Professional Advisory Committee (P.A. 84-315)

Public Act 84-315 has established a prospective payment system (PPS) for hospitals commencing in 1985, and also provides for the establishment of an advisory committee for the purpose of addressing such issues as changes in technology, clinical practice patterns and other changes affecting the delivery of hospital and medical care. The committee is to be appointed by the Governor with two physicians serving as representatives of CSMS. In conformance with a resolution passed by the House of Delegates, the Council VOTED to submit the names of Joseph C. Czarsty, M.D., President-Elect; James P. Orphanos, M.D., Vice-President; Edward A. Kamens, M.D., Delegate to the AMA; and Daniel W. Doctor, M.D., Past CSMS President, to the governor, strongly urging him to immediately appoint the Professional Advisory Committee and initiate its vital activities.

Unified Membership

The House of Delegates directed the Council of CSMS to establish, in cooperation with constituent county associations and the AMA, a program to promote the concept of unified membership and to increase awareness of the membership of the benefits and importance of belonging to their respective county medical associations, the CSMS and the AMA toward the objective that unified membership be accomplished. The Council is to report its activities in this area to the House of Delegates at its 1985 interim meeting. It was VOTED that the Ad Hoc Committee on Membership construct a program to achieve the aims of the action taken by the House of Delegates.

CSMS Annual Meeting—May 8, 9, 1985

A breakdown of the delegates' attendance at the subject meeting, which had also been forwarded to the county associations, was accepted for information.

Guy W. Van Syckle, M.D., who had requested time on the agenda to discuss certain aspects of the annual meeting, had to leave the Council meeting and, therefore, the item was tabled.

Date of 1986 Annual Meeting

It was VOTED that the 1986 Annual Meeting be held at the Park Plaza Hotel, New Haven, on May 7, 8, 1986.

Joint Statement of the AMA and the American Psychiatric Association

A joint statement of the subject organizations regarding the insanity defense was brought to the attention of the Council by Jerome K. Freedman, M.D. This subject was also to be discussed at the AMA House of Delegates meeting. It was VOTED to accept the report as information.

Attorney General's Opinion Concerning the Applicability of the New Reporting Law to Physicians Who Have Impaired Physicians as Patients

The new reporting law (P.A. 84-148), An Act Concerning the Reporting and Investigation of Complaints Against Physicians by the Department of Health Services, would appear to revoke the medical privacy of patients who are physicians. A copy of a draft opinion, which was prepared by Attorney Philip S. Walker, legal counsel of the Hartford County Medical Association, was distributed to all members of the Council. Following discussion, and since not all legal data was available, it was VOTED to table this item until the September Council meeting.

Committee on Drug Abuse Education

It was VOTED to appoint Gerald H. Flamm, M.D., New Haven, as Chairman of the subject committee. Dr. Louis A. Coulson, New London, could not accept the Chairmanship, but wished to remain on the committee.

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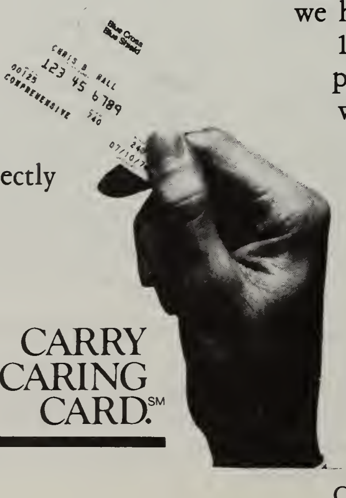

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Life Members

It was VOTED to receive for information the following names of Life Members:

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Frederick A. Beardsley	Willimantaic
Samuel Blank	Madison
Richard J. Brown	Stratford
Edward N. Diters	Collinsville
Stephen M. Donohue	Windsor
Carol Goldenthal	Hartford
George G. Haydock	Sharon
Herbert D. Lewis	New Haven
Norman M. Mann	West Hartford
Carl V. Pantaleo	New Haven
Ranald J.M. Steven	Hartford
Ellwood C. Weise	Stratford
Norman Zeldis	Hartford

Task Force on Health Care Liability Insurance

It was VOTED to name R. Leonard Kemler, M.D., Hartford to be the Society's representative on the Task Force on Health Care Liability Insurance. This Task Force was created by the 1985 General Assembly and is a 15 member group which will include one representative of CSMS. The Task Force will be funded for $10,000.

Dates of Future Council Meetings

Wednesday, September 4, 1985
Thursday, October 24, 1985

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on June 13, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Opportunity available in our 220-bed community hospital with an active prehospital care program for a full time emergency medicine trained or practice tract prepared physician. Our six full time physician staffed department has a volume of 28,000 visits annually. Excellent benefits and competitive salary are offered. Please send CV to Patricia C. Kuszler, M.D., Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT 06450.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

FAMILY PRACTICE

Board certified or eligible residency trained family physician wanted to associate with same in a growing town of 20,000 in the foothills of the Connecticut Berkshires. Established, growing practice—salaried first year; full partnership in second year. No OB. Send CV to P. Anderson, M.D., One Old Park Lane, New Milford, CT 06776.

Family physician to join board certified residency trained family practitioner in a growing, two office practice in Guilford or Essex on the shoreline. Beautiful area; enjoyable life style; excellent schools. Great opportunity for professional and personal satisfaction. Will consider part-time. Reply to, Alan Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

GENERAL PRACTICE

Southern CT area/Walk-In Medical Center seeks licensed physicians. Full and part time positions available days, evenings and weekends. Competitive salary. Please respond to CSMS, GP/JS.

GENERAL SURGERY

General Surgical practice opportunity in moderate-sized seacoast Connecticut town. Must be BC/BE. Send CV, etc. to CSMS, c/o SUR/VV.

INSTITUTIONAL MEDICINE

JCAH-Accredited 350-bed State Hospital seeks the services of a board eligible physician with experience or interest in Respiratory Therapy and a willingness to participate in limited administrative functions. Work week of five days, 35 hours with liberal State fringe benefits. Send C.V. to R.J. Cavalieri, M.D., Chief of Medicine, Veterans Home and Hospital, 287 West St., Rocky Hill, CT 06067.

Walk-In Medical Services is seeking full and part time physicians to work in a convenience medical facility in Orange, CT. FAM. PRAC/IM preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Internist—University-based HMO seeks inquiries and applications for staff positions. Competitive salary and benefits programs. Contact, Medical Director, Yale University Health Services, 17 Hillhouse Ave., New Haven, CT 06520 (Tel. 203-436-8433).

Internist. B.C. with some cardiologic training for full-time position with large Southern Connecticut company. Outstanding career opportunity for ambitious individual in occupational and corporate medicine. Reply to CSMS, Box IM/SSS.

Internist wanted to join group of three busy internists. Rural community with two universities in eastern Conn. 150-bed hospital. Send CV to Internal Medicine Group, 14 Quarry St., Willimantic, CT 06226.

Four physician medical group seeks BC/BE internist for primary care. Special training in Geriatrics or Immunology would be of interest but not necessary. Located in suburban SW Fairfield County, good schools, Yale Affiliate, teaching hospital. Favorable salary and benefits with eventual full partnership. Start July 1986. Send CV and letter stating career goals and salary requirements to CSMS, Box IM/GG.

MISCELLANEOUS

Wanted, to join three man medical group, board certified family physician or general internist. Please reply to: Ridgefield Medical Group, 38 Grove St., Ridgefield, CT 06877 or telephone (203) 438-6541.

Immediate position open full or part-time for physician for Ambulatory Care Center in Enfield, CT. Contact Robert S. Mausel, M.D., Medical Director, 15 Palomba Dr., Enfield, CT 06082 (203) 745-1684.

Two physicians needed: One with emphasis in Cardiology and the other in Family Medicine. Practice in underserved area in Connecticut. Full service center-active planning stages. Reply to: CSMS, MSC/AMD.

PEDIATRICS

BE/BC pediatrician wanted to join practice of three pediatricians and PNP in Middletown. Excellent salary and fringe benefits leading to full association. 350 bed community hospital with Level II nursery and F.P. residency program. Please send resume to Middlesex Pediatric Assoc., P.C., 80 South Main St., Middletown, CT 06457.

Pediatrician—Board eligible or certified to join group of three pediatricians in coastal Connecticut close to New York City. Competitive salary and benefits with early partnership. Reply to: CSMS, PED/RR.

PRACTICE FOR SALE

Ophthalmology practice for sale. Active surgical practice in eastern Connecticut. Modern office, solo but associated with town's other ophthalmologist. Moving for family reasons. Terms, negotiable. Send CV to Samuel Masters, M.D., P.O. Box 16, Willimantic, CT 06226.

General, active surgical practice for sale in southern Connecticut. Medium-sized city. Well equipped office including fully equipped minor surgical suite. Available July 1, 1985. Reply to CSMS, c/o SALE/BB.

Ob/Gyn solo practice and building for sale in northwest Connecticut. Gross $200,000 plus. Will help finance if needed. Reply to CSMS, SALE/FH.

PRIMARY CARE

Primary Care Physicians, BC/BE, needed to join expanding Walk-In Medical Center Group in central Connecticut. Full or part-time positions available. Compensation package includes competitive salary, malpractice insurance, and profit sharing opportunity. Stimulating work experience in a comfortable setting with flexible scheduling. Send C.V. to: PhysicianCare, 28 Main Street, East Hartford, Ct., 06118, or call (203) 569-8644.

Physicians – Rapidly expanding primary care centers in the Waterbury area. Looking for licensed physicians, full-time and part-time. Salary negotiable, dependent on experience. Send resume to: Family Walk-In Medical Center, 694 Straits Turnpike, Watertown, CT 06795.

PSYCHIATRY

Consulting psychiatrist for community-oriented psychosocial rehabilitation agency. Licensed required. Psychiatrists needed to provide three hours, every other week of consultation services at a facility serving the greater Norwich area. Clientele consists of poor, chronically mentally ill adults. Send inquiries to David Burnett, Executive Director, Reliance House, Inc., 132 Broadway, Norwich, CT 06360.

Child Psychiatrist needed for full to part-time, in greater Hartford area, to join a well established office and hospital practice. Reply to CSMS, PSY/MN.

RADIOLOGY

Part-time radiologist, board eligible or certified for private office practice in greater Hartford area. Please send CV to CSMS, RAD/CC.

Radiologist wanted part-time for general diagnostic radiology in private office practice in Waterbury area. All replies confidential. Write CSMS c/o RAD/AA.

Hospital based general diagnostic radiologist with special interest and training in invasive radiology is being recruited by six man radiology group for 100 plus general hospital in Northeastern Connecticut. Individual must have depth of experience necessary to initiate and manage interventional procedure program. Hospital offers nuclear medicine, ultrasound and mobile CT scan unit. Send curriculum vitae to Jonathan Berger, M.D., 142 Echo Dr., Vernon, CT 06066.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

ANESTHESIOLOGY

Immediately available. Age 31. AB elig. MD, G.S. Medical College; Int., Flushing Hospital of Medical Center, NY; Res., Albert-Einstein College of Medicine, NY; Fellowship, Maimonides Medical Center, NY. Prefers solo, group or associate type practice. Write, Vasant Chheda, M.D., 950 49th St., Apt. 8K, Brooklyn, NY 11219.

July '85. Age 39. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD, Bangalore Medical College, India; Res., Cheettenham General Hospital, Dryburn Hospital and Birmingham Accident Hospital, U.K.; Fellowship, Maimonides Medical Center, Brooklyn, NY. Interested in OB Anesthesia, Pediatric Anesthesia and General Surgery with a group, associate or institutional type practice. Write, Yellagondahalli Janardhan, M.D., Apt. 108, 34 Minebrook Rd., Edison, NY 08820.

Aug. '85. Age 33. Presently in practice. FLEX. AB elig. MD, Far Eastern University, Philippines; Int. and Res., State University of NY, Downstate Medical Center; Fellowship, State University of NY (OB and PED Anesthesia). Prefers solo or group type practice. Write, Frederick D. Moser, M.D., 143-47 Barclay Ave., Flushing, NY 11355.

FAMILY PRACTICE

Aug. '86. Age 28. Nat'l bds. AB elig. MD, State University of New York at Buffalo; Int. and Res., University of Maryland. Prefers group, associate, institutional, or industrial in a small to medium-sized community. Particularly interested in a coastal community but will consider all offers. Write, Anthony E. Turiano, M.D., 1411 West 37th St., Baltimore, MD 21211.

July '86. Age 30. FLEX. MD, Autonomous Univ. of Guadalajara, Mexico; Int., (Fifth Pathway) New Rochelle Hospital Medical Center, New Rochelle, NY; Res., The Williamsport Hospital, Williamsport, PA. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Francis C. Imbarrato, M.D., 505 Hawthorne Ave., Williamsport, PA 17701.

OBSTETRICS AND GYNECOLOGY

April '85. Age 30. Presently in practice. AB elig. MD, NY Medical College; Int. and Res., NY University/Bellevue Medical Center. Primarily interested in a group practice in a medium-sized community. Write, Andrew R. Herzog, M.D., 229 Haven Rd., Franklin Lakes, NJ 07417.

INTERNAL MEDICINE

July '85. Age 40. Licensed in Connecticut. Nat'l bds. AB elig. MD, Universidad Autonoma de Cd. Juarez, Mexico; Int. and Res., NY Medical College/Metropolitan Hospital, New York, NY. Prefers solo, group, associate or institutional type practice. Write, Marvin H. Lerner, M.D., 233 East 32nd St., #4J, New York, NY 10016.

GASTROENTEROLOGY. Oct. '85. Presently in practice. Nat'l bds. AB cert.(IM); AB elig. (GI). MD, University of South Dakota; Int., Res., and Fellowship, George Washington University. No preference to size or type of practice. Write, Howard L. Tice, M.D., 3260 Lovers Lane, Fayetteville, AK 72701.

OTOLARYNGOLOGY

July '85. Licenced in Connecticut. Age 33. Nat'l bds. AB cert. MD, New York University; Int., University of California, San Diego; Res., Yale University Medical Center; Fellowship, UCLA Prefers group or associate type practice in a large-sized community. Write, CSMS, IM/OTO.

PATHOLOGY

Aug. '85. Age 32. Nat'l bds. AB elig. MD, New York Medical College; Int., Brookdale Hospital, Brooklyn, NY; Res. St. Luke's Hospital, New York; Fellowship, Montefiore Hospital, Bronx, NY (Cytology). Prefers associate or institutional type practice. Write, Janet Schneller, M.D., 174 E. 206 St., Bronx, NY 10458.

PEDIATRICS

Immediately available. FLEX. AB cert. M.B.B.S., Medical College of Baroda, Baroda, India. Int., Medical College of Baroda; Res., Waterbury Hospital, Waterbury, CT and University of Medicine & Dentistry of NJ, Newark, NJ. Prefers solo, institutional or industrial type of practice. Write, Kirti M. Vora, M.D., 41 E. White Terrace, Nutley, NJ 07110.

Psychiatric Diagnosis in DSM-III

FRANK W. KNOBLAUCH, M.D.

ABSTRACT—The approach to psychiatric diagnosis delineated in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (Third Edition) is outlined and discussed with particular emphasis on the conceptual structure of DSM-III and its implicit logic. The major psychiatric diagnostic categories are described and some problems related to differential diagnosis in psychiatry are examined.

The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (Third Edition),[1] known as DSM-III, contains the current authorized American system of psychiatric classification. Published in 198O, DSM-III has profoundly affected the mental health field. Its categories and its logic are now ubiquitous aspects of psychiatric discussion; its assumptions, reasonable and otherwise, silently influence psychiatric thinking.

The "structure" of DSM-III, its conceptual framework, is an amalgam of old and new elements. Men naturally distinguish and categorize, and rudimentary diagnostic systems probably existed before recorded history. Hippocratic physicians described the choleric, sanguine, phlegmatic and melancholic temperaments (thought to be related to the four elements—Air, Water, Fire and Earth). In the fourth century B.C. Theophrastus Eresos described 30 character traits, such as laziness, tactlessness, querulousness, distrustfulness and the like.[2] Some of these early concepts proved more useful than others, particularly as physicians became increasingly interested in the possibilities of classifying and treating mental disorders.

Morel, a 19th century French physician, is said to have coined the term "demence precoce," to refer to an illness that Kraepelin later labeled dementia praecox and Bleuler called schizophrenia.[2] Physicians began to see mental disorders as like diseases, and named and described the various illnesses they believed they were encountering. Meanwhile, Freud was discovering the unconscious and numerous other concepts which, by their very universality, tended to change psychiatry's approach to taxonomy. Dementia praecox was seen as an illness one might or might not have but, according to Freud, everyone had an unconscious. Though he was a brilliant student of human psychology, Freud was not an avid cataloguer. His concepts were so abstract and so complexly interconnected that they lent themselves poorly to the inclusion/exclusion standards of diagnosis by category. He made an effort to describe various neuroses and later character traits, and some of these ideas have survived; however, a truly Freudian diagnostics is cumbersome. Anna Freud has published a complex diagnostic "inventory" based on traditional psychoanalytic conceptualization, but it is little used in this country.[3]

With DSM-III, neuroses are out and "disorders" are in. Its authors explain:

> "Because DSM-III is generally atheoretical with regard to etiology, it attempts to describe comprehensively what the manifestations of the mental disorders are, and only rarely attempts to account for *how* the disturbances come about, unless the mechanism is included in the definition of the disorder. This approach can be said to be "descriptive" in that the definitions of the disorders generally consist of descriptions of the clinical features of the disorders. These features are described at the lowest order of inference necessary to describe the characteristic features of the disorder".[1]

Increasingly concrete specification is preferred to esoteric abstraction. Those "manifestations" which can be delineated clearly are much valued, and in some categories we can determine with much greater reliability who does and does not meet the specific criteria for that disorder.

The Disorders of DSM-III

DSM-III is organized hierarchically. Table 1 summarizes the DSM-III taxonomy. Beginning with "disorders usually first evident in infancy, childhood and adolescence," the authors suggest considering first the

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FRANK W. KNOBLAUCH, M.D., Staff Psychiatrist, The Institute of Living Hartford, CT.

Table 1
OVERVIEW OF DSM-III CLASSIFICATION OF MENTAL DISORDERS

I.	*Disorders Usually First Evident in Infancy, Childhood or Adolescence*	*Organic Mental Disorders*	*Substance Use Disorders*	
	Developmental, Attention Deficit, Conduct, Eating, and other disorders	Dementias arising in the senium and presenium, Substance-induced OBS, OBS of unspecified etiology (Delirium, Dementia, Amnesic Syndrome, other organic syndromes)	Pathological use of or dependence on various substances	
II.	*Schizophrenias*	*Paranoid Disorders*	*Other Psychotic Disorders*	
	Disorganized, Catatonic, Paranoid, Undifferentiated, Residual types	Various types	Schizophreniform disorder, Brief reactive psychosis, Schizoaffective disorder, others	
III.	*Affective Disorders*	*Anxiety Disorders*	*Somatoform Disorders*	*Dissociative Disorders*
	Major depression, Bipolar disorder, others	Phobic disorders, Anxiety states, Post traumatic stress disorder	Somatization, Conversion, and other disorders	Psychogenic amnesia and fugue, Multiple personality, Depersonalization disorder
	Psychosexual Disorders	*Disorders of Impulse Control Not Elsewhere Classified*	*Personality Disorders*	
	Gender Identity Disorders, Paraphilias, Psychosexual Dysfunctions, and others	Pathological Gambling, Kleptomania, Pyromania, Explosive disorders, others	Paranoid, Histrionic, Narcissistic, Antisocial, Borderline, Compulsive disorders, and others	

three broad diagnostic groupings shown in row I of Table 1. Actually, as in diagnosis in other medical specialties, the sequence of "running through" a differential diagnostic list is arbitrary; the important thing is to consider, one group at a time, all the disorders which might account for the clinical phenomenon. DSM-III sequencing of the broad diagnostic groupings, though, is practical in that frequently decisions can be made quite quickly about whether row I or II disorders are likely to be present, allowing the clinician to move on to consider, in turn, the disorders listed in row III. "Appendix A" of DSM-III ("Decision Trees for Differential Diagnosis") is included "to aid the clinician in understanding the organization and hierarchical structure of the classification."

Psychotic Disorders

The word psychosis, the descendant of the Greek words psyche (breath, life, soul) and osis (a suffix denoting a condition or a process), is often defined by resort to concepts such as reality testing or delusion. The American Psychiatric Association's Psychiatric Glossary defines psychosis as

> " . . . a major mental disorder of organic or emotional origin in which a person's ability to think, respond emotionally, remember, communicate, interpret reality and behave appropriately is sufficiently impaired so as to interfere grossly with the capacity to meet the ordinary demands of life. Often characterized by regressive behavior, inappropriate mood, diminished impulse control, and such abnormal mental content as delusions and hallucinations, the term is applicable to conditions having a wide range of severity and duration."[4]

One's relation to "reality" is at issue here. Implicit in a decision that a patient "is psychotic" are value judgments concerning what sorts of thinking go beyond the bounds of coherence, which behaviors are inappropriate, which interpretations of reality are delusional. Important objections to such categorization have been raised (see, for example, Szasz's *The Myth of Mental Illness*[5]), but the clinical utility of the concept psychosis remains. In row II of Table 1 are listed those disorders which have psychotic features as an essential part of the clinical picture. A variety of other disorders may have such features as well (e.g., some major affective, some organic, and some childhood disorders) and ought to be considered in thinking through the diagnoses of patients who are or have been psychotic. In addition, the alterations to "reality" which occur in the "nonpsychotic" disorders can also verge on psychosis, though the disruptions here tend to be more transitory or perhaps circumscribed to particular areas (e.g., an overwhelming fear of flying in an otherwise "functional" and well-adjusted person).

The first step in approaching the diagnosis of patients "with psychotic features" ought to be descriptive—eliciting and defining such signs of psychotic thinking as delusions, hallucinations, incoherence, marked loosening of associations, poverty of thought content, markedly illogical thinking, or behavior that is bizarre or grossly disorganized. There has been an important and interesting literature reflecting major efforts to sharpen, differentiate and clarify cardinal signs and symptoms in hopes of devising a truly reliable way to separate, for example, a person "with schizophrenia" from another person who is psychotic due to some other condition. These searches for cardinal, pathognomonic, or "first rank" symptoms of schizophrenia have been disappointing. No system based on symptom picture alone can reliably distinguish schizophrenia from such imitators as mania or drug-related psychoses.

The DSM-III approach to schizophrenic disorders acknowledges such overlapping by requiring other classes of criteria here, such as (1) deteriorated function (e.g., at work, socially, or in terms of self care), (2) minimal duration of six months, (3) onset before age 45, and (4) several exclusion criteria. Diagnosis thus combines "cross-sectional" features (i.e., descriptions of the symptom picture at a particular time or phase of the illness), and longitudinal ones (allowing for categorization of disorders by their behavior over time). A delusional patient might be said to have a brief reactive psychosis if the psychosis follows a "psychosocial stressor" and lasts for less than two weeks. If the process goes on longer, but less than six months, a schizophreniform disorder may be diagnosed. Schizophrenic disorder requires a duration of at least six months.

Other disorders with psychotic features are distinguished in other ways: organic psychoses and drug-related psychoses by presumed etiology; certain malingering and factitious disorders by voluntary control of symptoms; various disorders by their preadult onset; paranoid disorders by delusions with persecutory or jealous content and by the absence of the more bizarre or disorganized thinking associated with schizophrenia; and the affective disorders with psychotic features mainly by the predominance of abnormal mood phenomena. In practice, of course, many patients seem to chart their courses right through our gray areas and zones of overlap. Distinguishing schizophrenic from schizoaffective from atypical bipolar disorder in a young patient, for example, can be extremely difficult—perhaps because we still understand so poorly nature's own categories of this sort.

Nonpsychotic Disorders

While the disorders of rows I and II in Table 1 can often lend themselves readily to being ruled in or out, the nonpsychotic disorders tend to encroach on each others' domains in ways which complicate inclusion/exclusion decisions. The following case illustrates some of the difficulties inherent in making a diagnosis in a nonpsychotic patient.

Case: a 40-year-old woman consults her internist because she has been feeling tense, anxious and not herself for months. She has abdominal pains and occasional bouts of diarrhea, but wonders whether these are just due to "nerves." The internist evaluates her abdominal complaints and finds no evidence of medical illness. Nothing suggests that the patient has a childhood onset disorder or an organic, substance use, or psychotic disorder.

The situation facing this internist is a common one for many physicians: there is a strong suggestion of a "functional" problem, and one of the symptoms, anxiety, may be the central finding—it might "underlie" many of the other symptoms. Will delineating the type of anxiety in question clarify the situation? There is an extensive literature on the problems of classifying anxiety, but anxiety is such a broad concept, and one so prône to subtle shifts in meaning and application, that the typologies of anxiety have substantial limitations as methods of differentiating nonpsychotic disorders. As described, this patient could have any of the nonpsychotic disorders shown in row III of Table 1.

A reasonable step with such a patient is to review and refine the history by focusing on symptoms which may not have seemed salient initially. Each of the broad groups in the DSM-III classification of nonpsychotic disorders (affective, anxiety, somatiaform, dissociative, psychosexual, and impulse disorders) can be seen as reflecting a separate model of illness or conceptual parameter. Each has a characteristic cluster of symptoms which tend to be present and are thus patterns against which the patient and her history need to be compared.

For example, this patient could have an affective disorder. The essential feature of affective disorders is a disturbance of mood ("a prolonged emotion that colors the whole psychic life; it generally involves either depression or elation"). However, anxiety is a common symptom of depression, and we should not be misled if it is given as the "chief complaint." The diagnostic criteria for major depressive episode are listed in Figure 1 (shown on the following page) to illustrate the descriptive orientation of DSM-III and to stress the need for clarity when describing the patient's specific signs and symptoms. This approach enables us to make more accurate assessments about the course of illness and response to treatment. "Depression" can be conceptualized from many theoretical starting points and its "features" are myriad. The category "major depression," however, highlights the illness analogy and suggests that whatever else we think the patient has we ought also to treat his depression.

Words, however, have a way of suggesting separateness where there may be none. Depressive disorders (included with the affective disorders) and anxiety disorders (in which by definition anxiety is the predominant symptom) are separate categories, suggesting two distinct domains of disturbed feelings. In practice, though, there is great overlap between anxiety and depression, and more de-

Figure 1

DIAGNOSTIC CRITERIA FOR MAJOR DEPRESSIVE EPISODE

A. Dysphoric mood or loss of interest or pleasure in all or almost all usual activities and pastimes. The dysphoric mood is characterized by symptoms such as the following: depressed, sad, blue, hopeless, low, down in the dumps, irritable. The mood disturbance must be prominent and relatively persistent, but not necessarily the most dominant symptom, and does not include momentary shifts from one dysphoric mood to another dysphoric mood, e.g., anxiety to depression to anger, such as are seen in states of acute psychotic turmoil.

B. At least four of the following symptoms have each been present nearly every day for a period of at least two weeks.
   1. Poor appetite or significant weight loss (when not dieting) or increased appetite or significant weight gain.
   2. Insomnia or hypersomnia.
   3. Psychomotor agitation or retardation (but not merely subjective feelings of restlessness or being slowed down).
   4. Loss of interest or pleasure in usual activities, or decrease in sexual drive not limited to a period when delusional or hallucinating.
   5. Loss of energy; fatigue.
   6. Feelings of worthlessness, self-reproach, or excessive or inappropriate guilt (either may be delusional).
   7. Complaints or evidence of diminished ability to think or concentrate, such as slowed thinking, or indecisiveness not associated with marked loosening of associations or incoherence.
   8. Recurrent thoughts of death, suicidal ideation, wishes to be dead, or suicide attempt.

C. Neither of the following dominate the clinical picture when an affective syndrome is absent (i.e., symptoms in criteria A and B above).
   1. Preoccupation with a mood-incongruent delusion or hallucination.
   2. Bizarre behavior.

D. Not superimposed on either Schizophrenia, Schizophreniform Disorder, or a Paranoid Disorder.

E. Not due to any Organic Mental Disorder or Uncomplicated Bereavement.

tailed inquiry about the patient's experiences is necessary. Patients often know an impressive amount about their anxieties. The clinical issue is to get them to detail all of this by asking the right questions. What seems to trigger anxiety? Are there fears or phobias (in particular, fears of being alone or of certain types of places or situations)? Are there obsessions? Is the anxiety like an attack (with notable physical concomitants, such as trembling, sweating, etc.), and how long does it last?

The somatoform disorders have as their essential features "physical symptoms suggesting physical disorder (hence, Somatoform) for which there are no demonstrable organic findings or known physiological mechanisms, and for which there is positive evidence, or a strong presumption, that the symptoms are linked to psychological factors or conflicts." Here again, it is important to look for a pattern, a repetitive, "disordered" way of life. For example, patients with somatization disorder report myriad symptoms to their physicians, and these "in the judgment of the clinician, are not adequately explained by physical disorder or physical injury, and are not side effects of medication, drugs or alcohol." Review of systems is crucial here; if our hypothetical patient has many unexplained physical symptoms, somatization disorder ought to be added to the differential diagnosis.

Dissociative disorders take as their essential feature "a sudden, temporary alteration in the normally integrated functions of consciousness, identity, or motor behavior." These can have quite strange or "crazy" features, such as in psychogenic fuge: "sudden unexpected travel away from one's home or customary place of work, with inability to recall one's past," and "assumption of a new identity" (partial or complete). If our patient were to add, for example, that she had been having trouble remembering certain things and found herself in places without knowing why or how she had gone there, a dissociative disorder should be considered. Here as elsewhere in DSM-III, reference to the diagnostic criteria sections for the disorders under consideration suggests the types of follow-up questions to ask. Similarly, if initial history-taking suggests difficulties with sexuality or with impulse control, reference to the diagnostic criteria sections for the psychosexual disorders or disorders of impulse control is useful.

The Personality Disorders

These disorders correspond to many of the time-honored ideas about people's "characters." The authors of DSM-III group the disorders into three clusters and suggest "individuals with paranoid, schizoid and schizotypal personality disorders often appear 'odd' or eccentric . . . individuals with histrionic, narcissistic, antisocial and borderline disorders often appear dramatic, emotional or erratic . . . individuals with avoidant, dependent, compulsive, and passive-aggressive personality disorders often appear anxious and fearful."

For the nonpsychiatrist, perhaps the most important question is whether the patient's "characteristic patterns of perceiving, relating to, and thinking about the environment and oneself" are at the root of his troubles. If the anxiety of our patient is, for example, part of a picture of pervasive suspiciousness and hypersensitivity, a paranoid personality disorder ought to be considered. Similarly, the other personality disorder types may also present with anxiety. Not surprisingly, the section of DSM-III describing personality disorders is among the most difficult to use. Diagnoses such as "mixed personality disorder with paranoid, narcissistic, and compulsive features" are common. Here, vagueness and inexactness in our taxonomy parallel the complex nature of the phenomenon we are attempting to capture in words.

Conclusions

In psychiatry, as in other medical specialties, diagnostic thinking shifts between data collection and attempts to fit known diseases and syndromes to the patient at hand. In practice, listening to the patient with several illness models in mind is the most useful means of narrowing the diagnostic field; not infrequently, only time—the course of illness—will tell.

Complexities involved in the interfacing of the various medical specialties pose an increasing dilemma to all physicians: how to be at least oriented in all major specialties so that we can understand the multiple dimensions of our patient's physical and psychological lives. Though the detail and jargon of DSM-III can be forbidding, it does provide a readable, comprehensible introduction to a host of psychiatric problems. Familiarity with the broad outlines of the system makes the diagnostic process more accurate and more comprehensive.

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Guidelines for the Pharmacological Management of Depression

WAYNE CREELMAN, M.D. AND JOHN W. GOETHE, M.D.

ABSTRACT—Depression is among the most common psychiatric disorders encountered by physicians. Symptoms of depression occur as part of "normal" responses to life events, and antidepressant medications are generally reserved for those individuals with "major" depression as defined in the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM—III) (See Figure 1 in Knoblauch, p. 564). The authors give prescribing guidelines for the primary pharmacologic agents used in treating depression: tricyclic antidepressants, TCA-like compounds, monoamine oxidase inhibitors, lithium carbonate and carbamazepine.

TRICYCLIC ANTIDEPRESSANTS AND RELATED COMPOUNDS

Mechanisms of Action

The tricyclic antidepressants were introduced in 1954, and approximately 20 variations of the basic tricyclic structure are now available. All tricyclics have two benzene rings joined by a seven-member ring, but there are also several nontricyclic antidepressants which are structurally distinct but clinically similar (Figure 1) All of these medications have in common three basic pharmacological actions (sedation, anticholinergic [antimuscarinic] effects and blockade of the amine pump), but they vary in their relative potencies (see Table 1).

Table 1
ANTIDEPRESSANT DOSAGE RANGES

Antidepressant *Generic*	*Trade*	*Starting* mg & Schedule*	*Acute* mg/day*	*Maintenance* mg/day*
Amitriptyline	Elavil	25 TID	150-300	50-100
Amoxapine	Asendin	50 TID	200-300	10-300
Desipramine	Norpramin	25 TID	150-300	25-150
Doxepin	Sinequan	25 TID	150-300	25-150
Imipramine	Tofranil	25 TID	150-300	25-150
Lithium	Eskalith	300 QID	1500-2400	900-1500
Maprotiline	Ludiomil	25 TID	150-225	25-150
Nortriptyline	Pamelor	25 TID	75-150	10-100
Protriptyline	Vivactyl	5 TID	30-60	5-40
Trazodone	Desyrel	50 TID	200-600	50-300
Trimipramine	Surmontil	25 TID	150-300	25-150
Phenelzine	Nardil	15 BID	45-90	15-45
Tranylcypromine	Parnate	10 BID	30-60	10-30

*Use one-half usual dose in geriatrics

The quality of sedation is more like that produced by the phenothiazines than the benzodiazepines and is a function of their peripheral alpha and histaminic receptor blocking actions. Doxepin, amitriptyline and imipramine, all tertiary amines, are the most sedating, while the secondary amines are less sedating, and protriptyline has no sedative action. Sedation is unrelated to antidepressant

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WAYNE CREELMAN, M.D., Psychopharmacology Consultant, The Institute of Living, Hartford, CT; Assistant Professor of Psychiatry, University of Connecticut. JOHN W. GOETHE, M.D., Director of Clinical Research, The Institute of Living; Associate Clinical Professor of Psychiatry, Yale University Medical School; Adjunct Clinical Professor of Psychiatry, Faculty, Division of Psychoanalytic Training, New York Medical College.

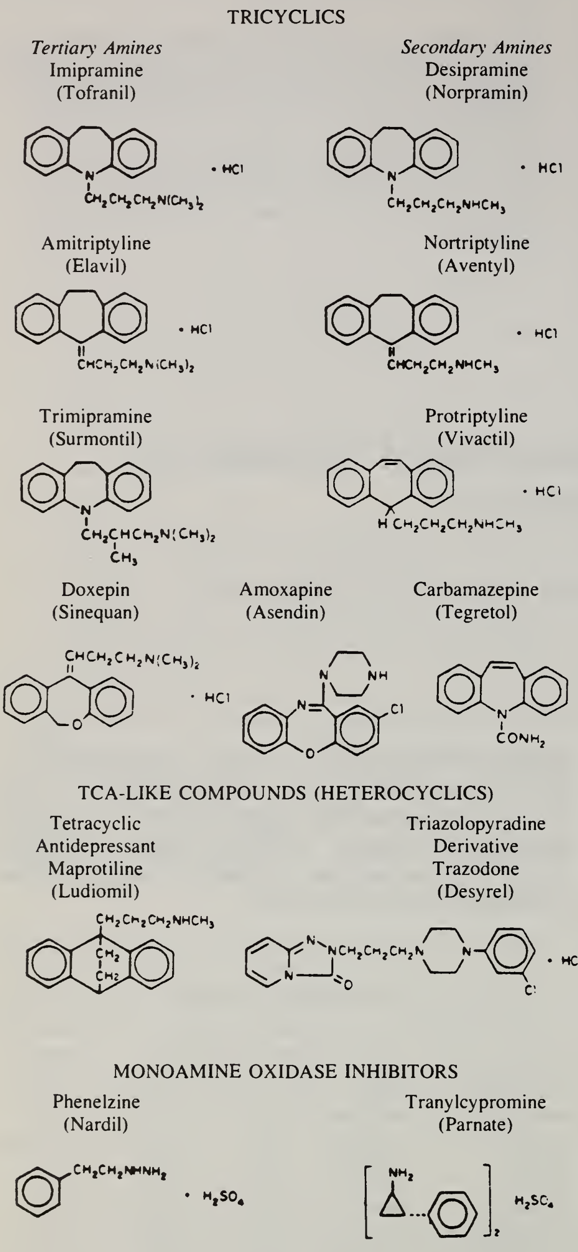

Figure 1
Antidepressant Medications

efficacy but is more important to consider in drug selection. Lethargic patients often prefer less sedating compounds, while patients with pronounced insomnia may benefit from the more sedative tricyclics.

The anticholinergic effects are principally due to antimuscarinic blockade, described in the following section.

The third action of these compounds results in blockade of the amine pump, involved in the active transport system of presynaptic peripheral neurons. This "pump" is likened to an "off switch" for terminating aminergic synaptic transmission, similar to the action of acetylcholinesterase in cholinergic neurons. Blockade of the pump explains some antidepressant effects, but recent research has focused on postsynaptic "down-regulation" which decreases the number of receptor sites in the noradrenergic system.[1] This mechanism accounts for the efficacy of those antidepressants which do not block the amine pump. Also, presynaptic blockade occurs rapidly while clinical response is often delayed several weeks, perhaps due to the time required for postsynaptic down-regulation.

Side Effects

Antimuscarinic effects can lead to dry mouth, sweating, constipation, urinary hesitancy and retention, delayed ejaculation and, in rare instances, adynamic ileus. The tetrad of mad as a hatter, blind as a bat, red as a beet, and dry as a bone characterizes the acute anticholinergic syndrome oftentimes associated with tricyclic overdose. Neurologic side effects are probably due to histaminic blockade, and confusion and mental status changes can occur at higher dosages, especially in individuals over the age of 40. Metabolic problems may also be secondary to histamine blockade; patients who gain weight on these medications complain of both increased appetite and carbohydrate craving.

Alpha adrenergic blockade of receptors in the cardiovascular system accounts for the three major cardiac side effects: orthostatic hypotension, tachycardia and malignant arrhythmias. Palpitations and tachycardia are typically associated with high plasma levels, while orthostatic hypotension is more often associated with dosages and plasma levels within the therapeutic range. Although low doses of tricyclic compounds exert a quinidine-like antiarrhythmic action with decreased PVCs, high doses are arrhythmogenic. Arrhythmias are secondary to lengthening of the H—V interval, which slows conduction through the AV node, delays cardiac repolarization and may lead to ventricular arrhythmias. Prolonged intracardiac intervals and flattening of T-waves are common with higher dosage. Cardiac toxicity results from both the anticholinergic and quinidine-like properties, with doses equivalent to 2500 mg of imipramine being potentially fatal. Despite the understandable concern about arrhymias, hypotension is a far more common side effect.[2] Orthostatic hypotension most often leads to relatively mild symptoms such as dizziness, but it can be serious, especially in older patients. Dizziness may occur in up to 30% of patients taking tricyclics,[3] and pronounced orthostatis has been reported in as many as 20% of patients in some studies.[2]

Prescribing Guidelines

The starting dosages and therapeutic ranges for the tricyclics vary somewhat (see Table 1), but for most of these compounds the initial daily dosage is 75 mg per day with an increase of 25 to 50 mg every one to three days. Some practitioners initiate treatment with a tid schedule,

Table 2

MAJOR ADVERSE EFFECTS OF ANTIDEPRESSANTS

Antidepressant	*Sedation*	*Anticholinergic*	*Cardiac*	*Hypotension*	*Other*
Amitriptyline	+ + + +	+ + + +	+ + + +	+ + +	
Amoxapine	+ + +	+ + +	+	+	EPS
Desipramine	+ +	+ +	+ + +	+ + +	
Doxepin	+ + + +	+ + + +	+ +	+ +	
Imipramine	+ + +	+ + +	+ + + +	+ + + +	
Lithium	+	0	+	0	Renal?
Maprotiline	+ + +	+ + +	+ + +	+ +	Rash, Seizure
Nortriptyline	+ + +	+ + +	+ + +	+	
Protriptyline	+	+ + +	+ + + +	+ + ?	
Trazodone	+ + +	0	+	+ + +	
Trimipramine	+ + + +	+ + + +	+ + + +	+ + + ?	
Phenelzine	+ +	0	0/ +	+ + +	Impotence
Tranylcypromine	0	0	0/ +	+ +	

but because of the long (approximately 24-hour) half-life, a once-a-day dosage regimen is effective. This approach is particularly useful in patients with insomnia, since a large dose of a sedating tricyclic can be given at bedtime. The once-a-day schedule decreases the likelihood of missed dosages and is also helpful in limiting daytime side effects. The full effect (side effects and beneficial effects) are often delayed, and some clinicians increase the medication to 150 mg per day and then observe the patient for one to two weeks before deciding if further increases are necessary. In any event, all patients should receive a maximum dose (or the maximum they are able to tolerate) for four to six weeks even if no immediate benefit is apparent. The first signs of response are usually improved sleep and appetite, with a reduction in nervousness and anxiety. After recovery, the antidepressant should be continued for at least six months and then withdrawn slowly while the patient is observed for signs of relapse.

Related Compounds

Amoxapine, maprotiline, and trazodone are "heterocyclic" compounds which are structurally different but clinically similar to the tricyclics. They are no more effective than other antidepressants, but they do offer a different side effect profile, and some patients who do not respond to tricyclics may respond to one of these newer drugs. Compared to the tricyclics, the heterocyclics show less sedation, less anticholinergic side effects, and possibly less cardiac toxicity.

Amoxapine is reputed to have a more rapid onset of action than other antidepressants. It is chemically related to the antipsychotic loxapine (Loxitane) and, in addition to its tricyclic-like effects, it blocks postsynaptic dopamine receptors, the assumed basis for the reports of galactorrhea, amenorrhea, dystonias, akathisia and parkinsonism. Ereshefsky has reported four cases of dyskinesia in women manifested by typical oral-buccal-facial dyskinesias, and in two patients the movements persisted for three months after discontinuation of the medication.[4] There have also been isolated case reports of first-degree AV block, left ventricular hypertrophy and atrial flutter, but these side effects are no more frequent than the cardiovascular side effects of the tricyclics. Overdoses with amoxapine have been associated with seizures and acute renal failure, sometimes requiring dialysis.[5,6]

Maprotiline is essentially a modified tricyclic structure with a side chain identical to desipramine. It also purports to have a more rapid onset of action, but as with amoxapine, its superiority in this regard has not been clearly established. Some reports suggest that maprotiline is particularly useful in patients with milder "neurotic" depressions or depressions associated with anxiety. Like desipramine, maprotiline selectively blocks the reuptake of norepinephrine and has virtually no serotonergic blocking action. It has an unusually long half-life (approximately 40 hours) and steady state is reached in about one week. The most common side effects are dry mouth and a maculopapular rash, which can be treated with short-term use of Benadryl. There have been approximately 100 reports of seizures, and although this represents less than 0.1% of treated patients, the incidence is higher than that associated with other antidepressants.[7] Seizures have been most frequently observed at dosages above 200 mg per day, and the maximum recommended daily dosage has recently been reduced to 225 mg. Gelenberg has suggested that maprotiline not be used in patients with abnormal electroencephalograms.[8]

Trazodone has a phenylpiperazine structure (see Figure 1). It has fewer anticholinergic side effects and theoretically less cardiotoxicity. Therefore, it may be the antidepressant of choice for geriatric patients and others who do not tolerate the common side effects. The drug appears to be less lethal and patients have survived massive overdoses. Trazodone is more sedating than other antidepressants, which is advantageous in some patients and problematic in others. There is increased GI irritation, but this can usually be overcome by taking the medication with meals. Trazodone's alpha-adrenergic blocking action results in a greater chance of postural hypotension, especially at high dosages, and there have been isolated reports of increased ventricular ectopic beats in patients with preexisting cardiac conditions. Higher dosages of trazodine, especially in the elderly, may cause impaired concentration, decreased memory, loss of interest and indecision. Priapism has been reported in 15 patients and five of these required surgical intervention with resulting impotence. The usual dosage of trazodone is 300 mg per day, and refractory patients may be given up to 600 mg per day.

MONOAMINE OXIDASE INHIBITORS

MAO inhibitors are effective antidepressants which have been underutilized because of inappropriate concern about their side effects. Overall, they have a much lower incidence of side effects than the tricyclics. The MAO inhibitor iproniazid was withdrawn from the market in the sixties because of its association with hepatotoxicity and hypertensive crisis. The true incidence of MAO-inhibtor induced hepatotoxicity has never been determined, and many of the early cases may have been due to epidemic hepatitis in mental hospitals. Hypertensive crises were due to patients ingesting foods with high tyramine content, or due to the co-administration of vasoactive drugs. The concern about hypertensive events has now been greatly reduced by increased vigilance in prescription practices and greater compliance with low tyramine diets.

Indications

MAO inhibitors are most frequently used in the treatment of atypical depressions and phobic conditions. However, a trial on an MAO inhibitor should be considered for any depressed patient unresponsive to other medications. Symptom profiles of patients likely to respond to this class of drugs include: initial insomnia, phobic symptoms, a worsening of depression in the latter part of the day, a low incidence of self-reproach, a low incidence of terminal insomnia, and a low incidence of worsening symptoms in the early morning hours. Other less predictable symptoms that suggest increased responsiveness to MAO inhibitors include: irritability, hypochondriasis, agitation, psychomotor retardation, hypersomnia and generalized anhedonia. Patients with agoraphobia, phobic anxiety, histeroid dysphoria, depressive neuroses, or reactive (nonendogenous) depression have responded to the class of medication.

Mechanisms of Action

MAO inhibitors block the monoamine oxidase-induced degradation of amine neurotransmitters, leading to presynaptic accumulation and an overall increase in amines. Platelet MAO activity has been studied as a possible measure of central nervous system MAO inhibition,[9] but this approach has limited clinical utility.

Side Effects

An advantage of this class of medications is the absence of anticholinergic side effects and the virtual absence of cardiotoxicity and electrocardiographic changes. Despite reservations about the use of MAO inhibitors in the elderly, MAO inhibitors are frequently better tolerated than tricyclics. As many as 50% of patients on MAO inhibitors may have mild to moderate insomnia. Thirty percent of patients complain of daytime sedation, which may be secondary to a direct effect of the medication, poor nighttime sleep, or the lethargy of depressive illness. Adjustments in the dosing schedule often remedy medication-induced sedation or insomnia.

Approximately 30% of patients complain of dry mouth. Orthostatic hypotension has been reported in 20-30% of patients, but this is generally only of clinical importance in patients over age 50, and fludrocortisone (Florinef) can be used to maintain adequate blood pressure if necessary. A marked increase in appetite and craving for carbohydrates can lead to weight gain, especially with phenelzine. Ten to 20% of male patients complain of impotence or pain with ejaculation, and 5-10% of women become anorgasmic. Both of these complaints are dose-related and may respond to reduction in dosage. The sexual complaints often resolve as tolerance develops, and the dose may then be increased slowly if necessary.

Most episodes of hypertensive crisis have occurred as the result of unintentional dietary lapses. The onset of the crisis is usually heralded by severe headache and can be treated with alpha-blocking agents, such as chlorpromazine, 25-50 mg intramuscularly, or phentolamine 5 mg IM or IV. A repeat dose may be required 30 minutes later, but two doses will usually control the blood pressure. Stimulant and vasoconstrictive drugs are contraindicated, and patients on MAO inhibitors should wear Medic-Alert bracelets.

Prescribing Guidelines

The two MAO inhibitors in common use are phenelzine (Nardil) and tranylcypromine (Parnate). As indicated in Table 1, the starting dose for phenelzine is 15 mg twice each day, with a maximum daily dosage of 90 mg. For tranylcypromine, the starting dose is 10 mg twice a day, with a maximum of 60 mg per day. The MAO inhibitors are almost always given in a divided regimen, and in most patients it is best to avoid nighttime doses. The optimal dose for any patient may be related to the amount of MAO inhibitor needed to suppress REM sleep, and for phenelzine this appears to be approximately one milligram per kilogram of body weight per day. As with the tricyclic antidepressants, the MAO inhibitors should be continued on a maintenance basis after the acute illness has resolved.

Phenelzine and tranylcypromine are structurally distinct (Figure 1), and patients who have not responded to one drug should be considered for a trial on the other. Patients refractory to tricyclics and MAO inhibitors individually sometimes respond to a combination of the two drugs. However, patients for whom such combined therapy seems indicated should usually be referred for pharmacological consultation.

OTHER MEDICATIONS USED IN DEPRESSION

Lithium Carbonate

Lithium carbonate is most widely used in the treatment of bipolar affective disorders (manic-depressive illness), but it has recently been accepted as an effective treatment for some depressed patients.[10] The usual starting dose is 300 mg twice or three times per day with careful monitoring of the serum level. The dosage can generally be increased by 300 mg every three to six days until a level of 0.8-1.2 mM/L has been obtained. Side effects which may occur at therapeutic doses include tremor, dizziness, increased thirst, and GI irritation with nausea and diarrhea. Mental confusion, coma and death can occur with toxic serum levels. Cinicians who are not experienced in prescribing lithium should obtain psychiatric consultation.

Carbamazepine

Carbamazepine (Tegretol) has been widely used in the treatment of partial complex seizure disorders. In the last several years, its efficacy in the treatment of bipolar disorders has been well established,[11] and patients with affective illnesses unresponsive to other medications may increasingly be given trials on carbamazepine. As is the case with lithium, clinicians unfamiliar with this medication should obtain consultation.

Electroconvulsive Therapy (ECT)

Although not a pharmacologic agent, ECT should be considered in all severely depressed patients. In the modern setting, ECT is a safe and efficacious treatment, and for a significant percentage of patients it is the treatment of choice.

CONCLUSION

Clinicians have a number of antidepressant medications from which to choose. Any selection should be based on careful diagnostic assessment and attention to the side effects as well as the therapeutic indications of the compounds under consideration. Response to antidepressants depends on adequate dosing, appropriate duration of treatment and follow-up. Nonresponsive patients often respond to alternate treatment regimens, and a combination of psychotherapy and drug therapy is usually more effective than either modality alone.[12, 13]

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Psychiatric Triage

CHARLES BOREN, M.D. AND PETER ZEMAN, M.D.

ABSTRACT – Successful psychiatric triage includes the rapid establishment of positive rapport between physician and patient. It also requires concerned, interested and receptive medical and nursing personnel. A pertinent history and mental status, focusing on the patient's current external and internal life events are essential. The physician should maintain a high index of suspicion for physical conditions which present with psychiatric symptomatology, necessitating a thorough physical evaluation. In situational crises, the evaluation itself may have sufficient therapeutic effect such that further treatment proves unnecessary. Referral of these cases to the family physician for follow-up, reassurance and support often is in order. In more severe psychiatric conditions (major affective disorder, schizophrenia, severe substance abuse, or serious character disorder), there should be a referral for a more in-depth consultation and, very likely, a more extensive psychotherapeutic and psychopharmacologic treatment program.

Triage is defined as "the screening and classification of sick, wounded, or injured persons during war or other disasters."[1] On the battlefield, medical personnel must decide which of the wounded will receive immediate, delayed, or (in the case of those whose wounds are too severe to be helped by the resources available) no treatment. In psychiatry, triage usually does not include the option of no treatment for the most severely "wounded" patients but rather involves decisions in the areas of immediate treatment and/or referral for subsequent therapy.

Although there is often overlap, it is useful to differentiate between triage and crisis resolution. Crisis resolution involves treatment that has as its goal the rapid amelioration of the acute situation which brought the patient to the therapist. Obviously, there are times when this improvement cannot occur rapidly, and appropriate triage centers on making an effective referral for further evaluation and treatment.

General Considerations

The setting in which the initial emergency evaluation occurs, the amount of time available, and the attitudes of the personnel are important determinants of success or failure of the triage process. The nature of the presenting problem is a major determinant in choosing the location. The physician's office may be more conducive to conducting the type of thoughtful, attentive interview that maximizes both assessment and patient cooperation. A possible limitation is the decreased availability of support personnel, laboratory facilities, and methods of control of the agitated or violent patient, such as restraints or parenteral medication. When one is uncertain about the degree of impairment, it is safer to choose the more controlled emergency room setting. If the evaluation takes place in the emergency room, distractions and the pressure of time may make it difficult to listen with sufficient care. Thus, the physician may fail to follow-up important leads or fail to develop the rapport necessary to facilitate the patient's and family's full cooperation in the evaluation process. Gersun and Bassuk[2] cite a study which found that dispositional decisions for over half of the patients seen in a large urban hospital were made in less than 15 minutes. These authors also stress that extended emergency evaluations decrease hospitalization rates and increase treatment acceptance.

The attitudes of the physician and the emergency room personnel are also critical to outcome of the evaluation process. Often they do not view the psychiatric patient or his presenting dilemma as a "real emergency" as they do a patient with severe chest pain or an acute abdomen. Psychiatric patients may be uncommunicative, angry, or

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CHARLES BOREN, M.D., Medical Director, The Institute of Living; Associate Professor of Psychiatry, University of Connecticut; Associate Clinical Professor of Psychiatry, Yale University School of Medicine. PETER ZEMAN, M.D., Director, Department of Psychiatric Education, The Institute of Living; Assistant Professor of Psychiatry, University of Connecticut.

suspicious. A number of them have had unhappy experiences with physicians and/or hospitals in the past. They are often accompanied by family members with whom they are in conflict. If the physician and/or hospital personnel are insufficiently trained, are under extreme work pressure, or have not come to terms with their anxiety, anger and other negative feelings toward patients with emotional disorders, the essential elements of a good triage consultation will not be present. The patient will not be the recipient of a calm, accepting, "listening attitude" from those in attendance. The physician may, at one extreme, procrastinate, letting patient and family sit around the emergency room while conclusions "fall into place" or he will "rush to judgment," making dispositional decisions based more on his internal needs and external pressures than on a careful evaluation of the patient's clinical situation.

The essential components of the initial evaluation include the psychiatric history (with a relevant mental status), the medical history and physical examination. The information thus obtained leads to a differential diagnosis, immediate treatment plan and long-range disposition, including a referral for further therapy if indicated.

History

The physician should make every effort to learn why the patient comes for evaluation at this particular time. Who defines the situation as an emergency—the patient, his family, friends, or law enforcement officials? What has broken down in the patient's interpersonal network and functional routine? Have his personal coping mechanisms and interpersonal support system broken down suddenly under a realistic or apparent pressure, or has there been a gradual deterioration of a tenuous adjustment?

As the examiner focuses on the current problem, he evaluates the objective severity of the stress (e.g., death of spouse or child, unexpected termination of employment) and the patient's subjective perception of his situation. It is helpful, and at times critical, to obtain history and an assessment of the patient's current situation from someone other than the patient, such as a member of his family. The physician assesses functional impairment at work, home or school; sudden or gradual changes in interpersonal relationships; drug and/or alcohol abuse; the patient's degree of understanding of his problems and their cause.

Family history may bring to light significant familial emotional disorders, such as severe depression, schizophrenia, and substance abuse. Elucidation of relationships with parents, siblings, spouse, and children contributes important clues as to the basis of the current problem.

It is important to inquire into the patient's interpersonal situation, in order to identify stresses, to evaluate the patient's weaknesses and strengths, and to determine the existence of or potential for a social support system. The patient may be vulnerable or inept in certain areas and surprisingly strong in others. Even if he appears quite vulnerable or helpless, he may do reasonably well if adequate support is available. In this context, the examiner should look carefully for evidence of impending losses or other threats in the patient's life situation.

Mental Status Examination

The mental status is used to clarify and evaluate more fully certain of the areas noted above. A thoughtless progression through an unselective complete mental status is not only unnecessary, but a "turn-off" to the patient. In contrast, a mental status carefully checking the areas of greatest concern often provides material that is essential to diagnosis and disposition. An evaluation of the patient's memory, orientation, abstracting ability, and perceptual status will go far in establishing the presence or absence of an organic brain syndrome, give clues as to its acuteness and guide the further work-up. If an adequate mental status is not done, subtle signs of psychosis (e.g., ideas of reference), early cognitive impairment, or masked depression with significant suicide potential may be missed.

The examining physician should note:

1. Appearance and behavior
2. Attention and concentration—level of consciousness
3. Thought process and content, including abstracting ability
4. Perceptual distortions
5. Mood—including presence/absence of suicidal thoughts/actions
6. Orientation and memory
7. Insight and understanding

Combining information obtained from the mental status and history allows the examiner to diagnose, or at least suspect, the presence or absence of organicity, significant affective disturbances (including suicide potential), or schizophrenic illness. He will also have an impression of the patient's ability to understand his situation and his willingness and ability to participate in treatment.

The Physical Examination in Psychiatric Triage

The physical examination and selected laboratory tests are essential components of the initial evaluation. Koranyl[3] found that 43% of 2090 psychiatric clinic patients had one or more physical illnesses. In 69% of situations, these medical illnesses contributed markedly to the patients' psychiatric condition. For example, undiagnosed diabetes mellitus resulted in sexual and marital difficulties, undetected hypoglycemia led to instability and quarrelsomeness, unrecognized thyrotoxicosis was the cause of a drug-resistant anxiety state, and a brain tumor was the cause of symptoms believed to be hysterical in nature (see Table 1).

Given these findings, it is incumbent upon the examining physician to be alert to the possibility of the coexistence of medical and emotional problems and to determine their interrelationship. Central to the detection

Table 1

SOME EXAMPLES OF PHYSICAL ILLNESS PRESENT IN PSYCHIATRIC CLINIC PATIENTS

Infective and Parasitic:	Hepatitis Syphilis Malaria Mononucleosis
Neoplasms:	Bronchogenic carcinoma Carcinoma of the stomach, pancreas, cervix, breast Brain tumors
Endocrine, Nutritional and Metabolic:	Diabetes mellitus Hypoglycemia Thyrotoxicosis Klinefelter's syndrome Alcoholic and nutritional vitamin deficiencies
Central Nervous System:	Epilepsy Postencephalitic states Demyelinating disease
Circulatory System:	Heart disease Cerebrovascular disease
Respiratory System:	Asthma Chronic obstructive lung disease
Digestive System:	Gastric and duodenal ulcer Hiatal hernia Colitis Cirrhosis of the liver Pancreatitis
Genitourinary System:	Acute and chronic nephritis Prostatitis Endometriosis
Musculoskeletal System and Connective Tissue:	Systemic lupus erythematosus

of a medical illness presenting with emotional symptoms is the examining physician's awareness of potential organic etiologies of emotional and behavioral disorders. The examining physician's preconceived ideas about patients with psychiatric problems may result in overlooking a significant medical etiology. While in the Navy, one of the authors was asked to consult on a case of a marine who was experiencing enuresis. The referring internist, concurring with the patient's superior officer, felt that this man was unfit, immature, and should be discharged from military service. However, he had done well in basic training, was highly motivated to remain in the Marine Corps and greatly embarrassed by the recent onset of bedwetting. Furthermore, he had not experienced enuresis as a child. In the month prior to the consultation, he had lost a significant amount of weight and experienced polyuria and polydipsia during the day as well as at night. Tests of the patient's urine and serum revealed glycosuria and an elevated blood sugar, confirming the diagnosis of diabetes mellitus. It must be kept in mind that there are times when an acute psychiatric condition can be misidentified as a physical disorder. On one occasion, one of the authors was called to the emergency room to evaluate a patient felt to have had "a stroke." Following the obtaining of history from a family member and successful treatment using hypnosis, the correct diagnosis was judged to be an acute dissociative reaction.

Although there are a great number of physical illnesses that may produce psychiatric symptoms, perhaps the most important attribute of the triage physician (given a fundamental level of diagnostic competence) is a high index of suspicion of a potential physical cause underlying the psychiatric disturbance. Almost equally important is the triage physician's understanding of the psychologic components of physical illness. In addition, one should note the patient's (and the family's) reaction to his physical symptoms. Inordinate concern should be investigated, as the patient may be expressing psychological distress or interpersonal conflict through somatic symptomatology. Seeming lack of concern, on the other hand, may be indicative of psychological efforts to control overwhelming feelings of panic and depression. In these situations, the triage physician should be *aware* of the presence of strong feelings beneath the surface but would usually elect *not* to press the patient himself to become conscious of them. The patient's reaction to the presence of physical symptoms may also provide meaningful clues as to his ability or willingness to cooperate with further diagnostic work-up and treatment.

In conducting the medical examination, the physician should pay special attention to the neurological, cardiovascular and endocrinological organ systems. The effects of alcohol and drug use, intoxication and withdrawal states, are also important in the differential diagnosis. The examining physician needs to be aware of the emotional difficulties, disorientation, perceptual disturbances and bizarre behavior that may be present in such diverse physical illnesses as systemic infections, chronic pulmonary diseases, cranial trauma, anemia, liver and kidney disease.

It is often difficult to do a physical examination on a disturbed or resistant patient, but vital signs, blood pressure, pupil size and reactivity, signs of head trauma, gait and station, pathologic reflexes, auscultation of the thorax, and presence or absence of organomegaly are central components of a triage physical examination. Important laboratory tests include CBC, urinalysis, blood sugar, BUN, liver function studies and urine for drug screening.

Common Psychiatric Emergencies

Generally, utilization of hospital emergency rooms by psychiatric patients has increased significantly in recent years. Early work at Yale indicated that the establishment of a mental health center increased visits to the psychiatric emergency room by offering greater continuity of care. Bristol noted a doubling of such visits between 1960 and 1970 (although there was a decline between 1970 and 1977, possibly because of increased outpatient services available at community mental health centers). Disposition results from Bristol's 1977 data are: hospitalization 41%; outpatient treatment 39%; no treatment 9%; other 11%.[4]

There are certain commonly occurring situations that present in a triage setting which deserve special mention. One of these is the assessment of the patient's dangerousness – to himself or to others. The patient's statements, either spontaneous or in response to clear, unambiguous questioning are to be taken seriously and, until otherwise proven, are the major guidelines as to immediate dangerousness. Once again, friends or family members often give valuable information with regard to past behavior or current expressed intentions. This information is especially critical if the patient is uncommunicative. Farberow and Shneidman[5] discuss in depth indicators of high lethality in a patient with suicidal impulses. They also discuss the management of this type of crisis. The presence of severe depression, psychosis, alcoholism, and loss are central "negative" factors in the assessment of suicidal risk. The presence of a support system, motivation, a sense of helplessness rather than hopelessness, future planning and ability to form a relationship with the examining physician are central "positive" factors.

Many of the same factors are also critical to the assessment of the patient's potential for harming others. Of particular importance is his past history in terms of assaultive behavior or verbal threats. A history of significant alcohol or drug abuse increases the likelihood of assaultive behavior, as does the presence of psychosis. If the patient reveals a persistent animosity toward another, particularly if he feels this person has wronged him, one must carefully assess not only the depth of the patient's anger but his ability to control it. The issue of dangerousness is one in which additional psychiatric consultation is apt to be of great importance.

Another common challenge confronting the triage physician is establishing the presence or absence of psychosis. If the patient's behavior is bizarre, if he is deluded, or if significant perceptual disturbances (e.g., visual or auditory hallucinations) are present, one has established that a psychosis is likely present, and one next attempts to determine the cause. Once again, we would emphasize the importance of checking carefully for the presence of an organic brain syndrome. Critical to this judgment are memory defects (especially immediate recall and recent memory), orientation (especially to place and person) and level of consciousness. The triage physician must satisfy himself with regard to presence or absence of organicity before he turns to the consideration of the other two common causes of psychosis – schizophrenia or affective disorder. From a practical standpoint, the triage physician usually is not required to differentiate with certainty between schizophrenia and affective disorder. For the most part, it is sufficient to establish the presence of psychosis and initiate a work-up that will rule organicity in or out. A psychiatric consultant will then be able to help with further diagnosis and advise as to hospitalization and treatment approach. For example, the psychiatric consultant should be able to recommend the appropriate psychopharmacological agent with which to treat the constellation of disabling symptoms.

It is likely that dangerousness and severity of psychotic symptomatology are the major "patient" factors which result in most of the triage decisions to hospitalize.[6] The presence or absence of a supportive interpersonal network in the patient's life and the presence or absence of experienced psychiatric emergency room personnel with availability of follow-up facilities are very significant "non-patient" factors in this decision.

If the patient is not thought to be psychotic, the examiner considers other questions such as: Is this a crisis in the life of a person with a chronic characterological disorder, or does this represent a stress reaction in a person who usually functions reasonably well? Can one identify the source of the stress? What are the patient's strengths, his usual coping mechanisms? How can one help him place his situation in perspective and utilize assets to the best advantage? In the otherwise well functioning individual in the midst of a crisis, the exploration of these questions in the course of the evaluation may be enough to help him regain his psychological equilibrium. In such patients, the evaluation may prove "curative" and further assessment and treatment may be unnecessary.

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Ongoing Intensive Hospital Treatment

RICHARD BRIDBURG, M.D.

ABSTRACT—This discussion addresses the need for long-term intensive hospital treatment for people with severe personality disorders and schizophrenia. In the former, because of entrenched defensive patterns which appear normal to the patient, restructuring of the personality must occur. In the latter, the building and developing of ego capacities is central. Both require time. Both require skilled individual and family treatment; but, most importantly, both require a hospital environment in which not only this can take place but which, in itself, is an essential part of the treatment. Maintaining the capacity to continue this kind of treatment in the economic climate of the foreseeable future presents an enormous challenge, but we must meet this challenge in order to provide a necessary service.

Introduction

Despite the wish that all of the emotionally ill could be treated with brief outpatient psychotherapy, medication, crisis intervention, or other short-term strategy, there is still a large number of patients for whom these approaches are insufficient and who require long-term, intensive inpatient treatment.

A distinction must be made between those who require custodial care and those who show improvement through treatment over time—i.e., those for whom there is prognostic hope of a return to functioning in society and substantial improvement in the quality of life. The majority of cases treated on a long-term intensive inpatient basis fall into three categories:

1. Adolescents who are beginning to develop personality disorders;
2. Young adults with personality disorders;
3. Adolescents and young adults with one or other form of schizophrenia.

The balance of this discussion will be devoted to the explication of the long-term intensive hospital experience, why it is necessary for some patients and what it is that is provided in this setting which is not available through other therapeutic approaches.

Personality Disorders

"There is no present or future—only the past happening over and over—now." At first glance, this quotation, mouthed by an alcoholic in Eugene O'Neil's "A Moon for the Misbegotten" seems very depressing. It alludes to what Freud called an unconscious repetition compulsion.[1] Free will is limited by the degree to which we are doomed to repeat automatically patterns of behavior in a stereotyped way without knowing why. This unconscious repetition constitutes a psychological jail.

In order to understand how O'Neil's comment can be seen as hopeful rather than pessimistic, it is important to understand how the personality develops. Personality (or character) refers to that part of us which is the most stable and enduring. When we watch a play, we get to know the characters, and if anyone steps out of character or becomes essentially different in the course of the play, it jars us. We cannot accept the change unless there is an overriding reason which makes it abundantly clear why a character might become "different."

While each child comes into the world with an innate genetic endowment, the family setting into which he arrives also determines the ultimate personality type he will develop. It is primarily within the family that the individual is socialized. It is there that he wishes to feel loved, and it is there that he makes his important (unconscious) identifications. Children are extremely sensitive to the nuances of feelings in the home. They are "tuned in" to the "atmosphere," what is said and not said, what might lead to loss of love, to a cold parental look of displeasure, an action taken against a sibling, and so on. Children learn how to deal with the gamut of human feelings, thoughts and behavior in the narrow world of the family in such a way as to minimize anxiety in that

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RICHARD BRIDBURG, M.D., Division Director, Admissions and Consultation, The Institute of Living, Hartford, CT.

arena. Thus, from an early age children develop patterns of coping (also referred to as defenses or "character armor"[2]) in response to the enduring personalities of their parents and the family atmosphere.

People have at their disposal a variety of defenses against anxiety emanating from underlying conflicts and from the affects (feeling tones) connected with them. In personality disorders, fewer defenses (different clusters in different personality types) are available. They are used repetitively and automatically, whenever anxiety is aroused, and they become woven into the personality and lead to a pathologic "life style."[3] Parents of people with severe character pathology tend to show rigid patterns of behavior influenced by the generation from which they came, and there are classic family constellations for each type of personality disorder.

No matter how abnormal a patient's personality may seem to us, to him it seems perfectly normal. This is the key. Patterns, learned over a lifetime, and now unconscious, automatic and repetitive can, *if recognized,* be undone and relearning can take place. While it takes considerable time, there is hope if the patient can come to recognize consciously that the past is "happening over and over now."

Patients do not seek treatment for their personality disorders. Rather, they come for relief of symptoms that develop when their modes of interaction and the way in which they handle conflict, stress and feelings within the family do not work for them in life beyond the family. For example, people with compulsive personality disorders do not recognize the unconscious wish to be loved manifested in their striving for perfection and their constant self-criticism. Nor do they wish to change their attitudes which are reflected in language replete with words like should, ought, good, bad, must, have to, or what Karen Horney called "the tyranny of the should."[4] Such patients come for treatment because of symptoms of depression, indecisiveness, lack of pleasure in their lives, anxious preoccupation with details, and because of overwork and difficulty in expressing emotions.

Similarly, individuals with borderline personality disorders do not recognize their unconscious and pervasive fear of abandonment, their internal splitting of their self-image into good and evil parts, their projection of these parts onto others so that others are seen as totally good or bad. That their tendency to do this is automatic and repetitive and that this pattern underlies problem behaviors and symptoms such as impulsivity, suicide attempts, emptiness, boredom, patterns of unstable relationships, the inability to be alone, intense rage, and symptoms of identity diffusion escapes them. These patients seek treatment for their symptoms, not for their underlying personality disorders. Such treatment may have limited success, but it is highly likely that the symptoms will recur if the abnormal personality traits from which they spring are left untouched.

Since the past repeats in the present, we know that the way in which the patient has lived his life will be reenacted in the hospital setting. Thus, we take a detailed history of his behavior and style of interacting with his parents, other authority figures, siblings and peers. We need to know how he developed psychologically, what his parents' personalities are like, how he was disciplined, what kinds of family transactions are repetitive, how feelings are handled. The more we know, the more we can anticipate his likely interactions with his individual therapist and with nurses and fellow patients. A case report of a patient with an antisocial personality will illustrate many of these points.

Case Report

Bob, age 19, has stolen from his parents for years, lies persistently, has no close friends, runs with a bad crowd and gets other kids into trouble. He has a history of arrests, running away and explusion from school. He is charming, never learns from his mistakes, seems to have no conscience, doesn't seem to worry about anything, and always seems to be working on one ingenius scheme or another.

His parents are at their wit's end. They have "tried everything" without success. His father, aged 50, is a respected judge who is known to be tough in the courtroom and active in his community. As he recounts his son's misdeeds, he unknowingly smiles. He is getting vicarious pleasure from his boy's behavior. When he was a boy, he had "cut up" quite a bit, too. Whenever Bob gets into trouble, his father bails him out, warning him each time that this is "definitely the last time." Sometimes he punishes him severely, but it doesn't seem to make any difference. Bob's mother feels guilty about her part in her son's difficulties. She cannot control him. She worries a lot about what will become of him. She reports that she and her husband constantly argue about what they should do. The most consistent and repetitive family transaction proceeds as follows:

Bob acts up and gets caught. He claims his innocence, rationalizes and minimizes his role in the behavior. This exasperates his father who then angrily hands down a punishment. Bob then goes to his mother, plays on her guilt, pointing out how harsh his father has been for such a "little" thing. She, in turn, argues with the father, they fight and become split, and the punishment is undone. When outsiders are involved, the father might bail him out of trouble publicly at the same time as he punishes him at home privately. Inconsistent discipline is a consistent theme.

It is clear that Bob has never had to learn from his experiences because he was never forced to take responsibility for his actions, and he remains relatively free of anxiety because his punishment never "sticks." He has learned how to use people by evoking guilt in them. His acting up behavior is being subtly encouraged by his father. Adelaide Johnson has written extensively on the unconscious superego difficulty with which Bob contends. She describes the antisocial personality as having superego lacunae[5-7] or holes. The formed superego has two parts, a conscience and an ego ideal, both of which evolve partly through unconscious identification with the father. Bob has internalized his father's ambivalent attitude toward antisocial behavior, leading to a very rigid conscience which is in conflict with a distorted ego ideal. Bob is, therefore, unaware of a continuing conflict within him to act out. If he behaves well he is consciously pleasing his father. If he acts up, he is unconsciously pleasing him.

Hospital Treatment. The methods by which Bob operates will be automatically reenacted in the hospital.

He has no other choice. He is who he is. When he attempts to manipulate, he may wish to believe that he is in control, but it is a spurious control because he knows no other way to behave. It is this that he must come to understand, and the understanding will make him feel anxious and depressed because he will no longer feel he is in control. He can then become aware of the internal issues and conflicts, unlearn patterns of behavior and interaction, and learn new ones.

When Bob is caught breaking rules, the facts must be place in front of him without ambivalence. He has to come to know that his attempts to "weasel out" won't work and that he cannot stimulate guilt in those treating him or split them in their unified purpose. Limit setting must be clear and consistent. There can be no bail-outs. His family needs to be educated, including helping his father to recognize his ambivalent attitude toward his son's behavior and the vicarious gratification he obtains from it, and the mother to understand her tendency to allow herself to be manipulated through guilt. They must understand why a unified approach and consistent limit setting are necessary and must support treatment if it is to work. Appeals to the father or mother to bail him out or to undo limit setting must be resisted. He then becomes anxious as his usual mechanisms do not work. He is placed in a situation in which he must take responsibility for his behavior and can, therefore, learn. If he is asked what he thinks he deserves, his rigid conscience is revealed as he prescribes much more stringent punishments than those treating him would see as reasonable or useful.

In a nutshell, the patient must be contained in a structured environment with sufficient staff to monitor thoroughly his behavior and style of interaction. The focus in individual therapy sessions, in family and group therapy, on the unit and in the rehabilitational and school classes must be an integrated one. All caretakers should be working constantly in the same direction and repetitively making the same observations to the patient and connecting them to similar past behavior until he recognizes that his personality style is the problem, not just his symptoms or others' complaints. The more focused and integrated the interventions, the quicker will be the patient's realization, especially if his parents can recognize the need for change. It is a total hospital effort and cannot be effected, even by an excellent psychotherapist, alone. In severe cases, this phase of treatment on the most structured unit usually lasts from 9 to 18 months. If the patient is discharged too soon, old patterns are very likely to reassert themselves.

Schizophrenia

Schizophrenia is the name given to a group of disorders with a variety of symptom clusters. There are those types which have heavy genetic loading, often with a chronic course and a poor outcome. There are those cases in which there is less evidence for genetic factors and more obvious environmental factors and in which the prognosis is better. Though such characterization is simplistic, it can be useful in sorting out those patients who benefit from intensive inpatient treatment.

Some schizophrenic patients do best with a drug treatment regime, supportive outpatient psychotherapy, brief hospitalizations for acute decompensations, and a psychoeducational family approach, i.e., teaching the family about the illness and enlisting their support as educated co-therapists. Other schizophrenic patients appear to be more affected by environmental factors and are more likely to respond to intensive inpatient treatment. Major tranquilizers are frequently used to enhance the development of a therapeutic relationship, but the idea emphasized by Edith Jacobson[8] that psychosis can be seen as a defense against painful reality is also important. Psychotic patients can be understood and communication can occur. Harry Stack Sullivan[9-11] and Frieda Fromm-Reichman[12] stressed that psychotic productions and apparently disconnected thoughts have meaning. The central problem is that there is a serious impairment in the development of ego functioning, especially in the ability to modulate internal stress and feelings and to perceive reality and adapt to it.

The Family. In the typical family with a schizophrenic member, neither parent has emancipated himself from his own family of origin. Neither parent can take responsibility for his thoughts, feelings and actions, which leads to frequent defensive blaming and to scapegoating. The parents have little sense of their own identity and tend to act out designated roles in relating (what Wynne[13] refers to as "pseudomutuality") and, therefore, tend to be poor role models. The high anxiety level and personal concern about basic competence make it extremely difficult for the parents to give nurturance. Not uncommonly, one parent will be strongly dominant, with the other passively following, so that the child always faces the parents in a combined adversarial stance. Alternately, the struggle for dominance is never ending, each parent constantly undercutting the other, so that the child is fearfully drawn first to one parent's side and then the other's. Each seeks the child's loyalty.[14]

There is a high level of tension in the family most of the time, each member being highly sensitive to slights or criticisms with relatively little capacity to empathize. Bowen[15, 16] refers to the family as an "undifferentiated ego mass" where boundaries between people are unclear; they intrude on each other's business, speak for each other, negate each other's individuality. Problem solving is very poor when the issue has an emotional overlay and unresolved problems abound. Personal growth and movement toward independence are seen as threatening, while continued dependency is equally disfavored, causing an interminable Catch-22 situation, or what Bateson, et al.[17] call a continual "double-bind." Communication is unclear, with frequent verbal and nonverbal contradictions. The dangers within the family are projected outside so that the world is viewed with suspicion. This leads to an overprotection of the child from the apparently dangerous outside world, thus reducing his opportunities for socialization and for consensual validation (confirming what is true or real and what is not) outside the family.

The Patient. What is the impact of living in such a family system, combined with the genetic and the biologic propensity for psychosis? Usually the patient has a different philosophy of life from most people, a different myth/belief system based on the personal experience of his upbringing which has been generalized. He does not expect to be heard seriously. He believes that what he thinks, feels and does is of little or no significance. If he reaches out to share his pain, he expects to be disappointed. He cannot trust people. As his isolation increases, he develops a rich fantasy life. He has difficulty distinguishing reality from unreality. All feelings are dangerous and anxiety-provoking. He has no sense of being an integrated human being with a range of attributes, liabilities and feelings. To him, feeling irritated or attempting to be slightly self-assertive is frightening. Because these feelings have been negated so frequently, he cannot put them into a wider context and to him they mean that he is evil. He does not have a sense of proportion born of the experience of adequate nurturing. He thinks in absolute terms. Things are black or white and often can change from one to the other in seconds. He is frightened that his thoughts in and of themselves could have destructive effects.

The schizophrenic patient is filled with paradoxes. He is caught between the pain of loneliness and the intense fear of interpersonal contact. He is frightened that he might lose control of his impulses and equally frightened that he might be controlled by others. For him, pleasure is merely the relief of anxiety. He is guilt-ridden. Whatever he thinks or feels or does, he expects to be blamed. Closeness is dangerous. Often he feels incompetent and frightened that he might be homosexual. He has no expectation that he can gain comfort by sharing his problems and pain with others or that relationships can be different. He has no idea that there are reasons for his intense fear and the confusing thoughts and feelings, no idea why this is all happening to him. He is overwhelmed; his sense of self-esteem barely exists. The gradual move into psychosis is, in part, an escape from the pain of his reality.

Ongoing Intensive Hospital Treatment. In the most fundamental sense, a person's self-esteem improves when he comes to believe that his essence as a human being (what he thinks, feels and does) is respected and taken seriously by someone he respects. Nowhere is it more true than in the treatment of schizophrenia that the integrity of the therapist is paramount. The therapist must expect to earn the trust of the patient. His professional degree is insufficient! He must listen very carefully. He must be clear, say what he means and does not mean, and follow through on what he says he will do and not do. He must recognize the patient's dilemmas and bring his understanding of them to the patient until he feels understood. He must monitor the patient's real capacities and be careful not to ask him to function beyond those capacities lest he fail, feel overwhelmed and his self-esteem suffer. He must have the skill to understand the meaning of psychotic ideas and behavior and become the patient's bridge to reality by helping him, in an educative way, to understand the issues with which he struggles. He thereby helps the patient to develop a sense of internal organization that replaces the feelings of chaos.

As genuine empathy is felt, the patient slowly develops a trusting relationship which provides consensual validation, calms him, gradually reduces his intense interpersonal fears, and helps him to allow himself to feel and to understand and integrate his feelings. As the therapeutic relationship grows and the patient experiences empathy and an entirely different kind of human contact, he can then begin to risk attempting to relate differently with others and test his past assumptions about people in the therapeutic environment provided for him. The hospital milieu is essential for this slow, step-by-step process as it could not take place in an environment which reinforces the patient's old patterns.

The milieu in which the patient lives during treatment must be designed with purpose. Milieu is not a vague concept. It is created by people. The nurses and technicians, the occupational therapist, unit administrator and social worker must combine to form an integrated team. Each member of the team must have a thorough understanding of the pathology and a treatment plan must be designed to permit each discipline to bring its particular skill to the patient in an empathic atmosphere. Clarity, structure, stability and calm are reinforced. Tolerance for intense anxiety and the capacity to handle intense negative feelings without rejecting the patient are most important.

The level of functioning expected from and the degree of freedom and responsibility afforded to the patient must be closely monitored. Too much leads to regression; too little inhibits growth. Community meetings and activities afford the opportunity for gradual socialization and useful occupation. The unit staff must be skilled in the handling of group interaction, must interpret and clarify communications and be able to take charge of volatile situations without being threatening. It is particularly important that all staff members recognize that they are models with whom the patient identifies and that the patient needs to feel he is treated with respect. Family treatment is complex and must focus not only on understanding the patient but also on helping the parents through their pain and guilt toward greater personal growth, emancipation and acceptance of personal responsibility.

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The Diagnosis and Treatment of Behavioral Disturbances in the Elderly

WALTER A. KECKICH, M.D. AND HARRY E. MORGAN, M.D.

ABSTRACT—The elderly are the most frequent users of medical services. The physician faces a demographic imperative to provide services for an aging population. The attitude of health care workers in approaching the aged patient is one of the most critical factors in determining successful diagnosis and treatment. The authors describe the three most common syndromes in geriatric psychiatry—adjustment disorders, affective disorders, and organic brain disorders. The differential diagnosis and management of each disorder is discussed. Special emphasis is given to the details of aggressive diagnostic evaluation of organic brain syndromes and dementias including Alzheimer's Disease. In geriatric psychiatry there is good reason to be thorough in diagnosis, optimistic in approach, and persistent in treatment. Most psychiatric illness in the elderly can be effectively managed and often cured if properly diagnosed and treated.

The elderly are the most frequent users of medical services. There are presently over 29 million persons over the age of 65 in the United States. This group represents the most rapidly growing segment of our population and it is expected to grow to 20% of the total population in the next 30 years. Some areas in Connecticut, e.g., greater Hartford, will experience a 33% increase between 1980 and 1990 in this age group. The health care system and physicians in particular face a demographic imperative to design and provide a broad range of services for this aging population.

Attitudes and Biases

The attitude of the health care worker in approaching the aged patient is one of the most critical factors in determining successful diagnosis and treatment. Unfortunately, in the health network, the impaired older individual often meets clinical nihilism, a state in which there is a tendency to accept pathologic changes rather than to explore diagnostic possibilities and therapeutic interventions. The nihilism represents age bias and is fed by the professional's belief that there is nothing that can be done for an older patient. Thus, in the case of a problem such as dementia, potentially reversible causes are overlooked because of the commonly held myth that all elderly people develop "senility" if they live long enough. Rather than being a normal part of aging, dementia develops in only 20% of the elderly over 85. Even when

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WALTER A. KECKICH, M.D., Division Director, Acute and Ambulatory Services, The Institute of Living, Assistant Professor of Psychiatry, University of Connecticut. HARRY E. MORGAN, M.D., Director, Psychogeriatric Services, The Institute of Living, Assistant Professor of Psychiatry, University of Connecticut.

a proper diagnosis of an irreversible dementia is made, it is common to see no therapeutic interventions instituted for either the family or the patient from a mental health perspective.

In order to properly diagnose and treat an older population, physicians and all health care workers must set aside this pervading issue of diagnostic and therapeutic nihilism in favor of a more accurate view of the efficacy of interventions with the elderly.

Diagnostic Overview

In approaching diagnosis in the elderly, it must first be understood that the average patient over the age of 65 has 2.5 medical illnesses in addition to the behavioral or emotional disturbance they are presenting. Clinicians must explore *all* of the medical and psychiatric diagnoses, and understand their interplay, in order to design a treatment plan. In evaluating psychiatric diagnosis we find it useful to divide DSM-III diagnoses into seven broad categories:

1) Adjustment disorders, 2) Affective disorders,
3) Organic brain disorders, 4) Anxiety disorders,
5) Schizophrenic disorders, 6) Personality disorders,
7) Substance abuse disorders.

Once these broad categories are established, a focus on the specific diagnosis within that category can be accomplished. This article will focus on the three most common categories for Geriatric Psychiatry.

Adjustment Disorders

Adjustment disorder with depression is the most common psychiatric problem in the elderly. It must be differentiated from major depressive disorder mentioned below. Adjustment disorders are time-limited and usually related to an overt and external loss, usually the death of a spouse or close relative or friend. In the initial stages of grief, it is appropriate to use anxiolytics and sedative/hypnotics to assist the person with grief work. Psychotherapy is the primary modality used in resolving adjustment disorders and short-term medication management is used only as an adjunct. We prefer the judicious use of short-acting benzodiazepines especially at bedtime to allow for adequate sleep and to avoid excessive daytime sedation and numbing. If the signs and symptoms of depression with an adjustment disorder continue beyond six weeks, one must begin to consider an evolving major depressive disorder and a shift to antidepressant medications (see below) since the anxiolytics and the sedative/hypnotics are depressant medications.

Depression in the Elderly

The second most common psychiatric illness in the elderly is major depressive disorder. It sometimes masquerades as pseudodementia which is covered below. The classic signs and symptoms of major depressive disorder include loss of appetite, loss of weight, disturbed sleep, psychomotor agitation or retardation, loss of libido, anhedonia, fatigue and loss of energy, feelings of worthlessness and guilt, decreased concentration and memory loss, and suicidal thoughts, threats or attempts. The elderly frequently present with somatic manifestations such as chronic headache, vague cardiopulmonary symptoms and nonspecific gastrointestinal complaints. Many times they actually deny the feeling of depression but have many of the other mentioned major signs of depression. They often rationalize the feeling of depression by saying, "If you were this physically ill, you'd be depressed too."

Management of depression involves individual psychotherapy, family/marital therapy and medications, focusing on any loss which may have preceded the onset of symptoms. Medications alone or psychotherapies alone are not as effective as medications plus psychotherapies.[1,2] Antidepressant medications are chosen on the basis of the patient's physical illness, and the patient's ability to tolerate the potential side effects of the medication prescribed (see Table 2 in Creelman and Goethe, p. 567). Previous response to an antidepressant is a good predictor of future response. The tricyclic and tetracyclic antidepressants fall into two major categories – the norepinephrine reuptake inhibitors and the serotonin reuptake inhibitors (see Table 2, p. 567). The monoamine oxidase inhibitors are also effective antidepressants but usually used as a second line of defense in treatment resistant depressions because of the need for a special tyramine-free diet and the potential for hypertensive crisis if this diet is not followed closely.

Electroconvulsive therapy is felt to be the treatment of choice in many cases of major depressive disorder, especially with psychotic features. It is effective in treating 80% of the major depressive disorders with psychotic features[3] and presents mainly the risk of brief anesthesia in a discrete and controlled setting. It is usually safer to use electroconvulsive therapy in patients with severe cardiac illness than it is to use antidepressant medications. Discrete short-term memory loss from ECT is a definite side effect, especially in the elderly, but it is not a permanent loss, as function usually returns to normal in a few weeks. Many patients do remain permanently amnestic regarding the period of their ECT and the period of their psychotic depression, but recent and past memory outside of this period are usually fully functional within a few weeks (no more than 6 months) post-ECT.

Evaluation of Organic Brain Syndrome

Organic brain syndrome is a symptom complex and not a diagnosis. One must look for the causes of organic brain syndrome and proceed with a diagnostic protocol leading to an accurate diagnosis. Table 1 outlines a flow chart for the diagnosis of dementia. There are five key signs and symptoms of organic brain syndrome:

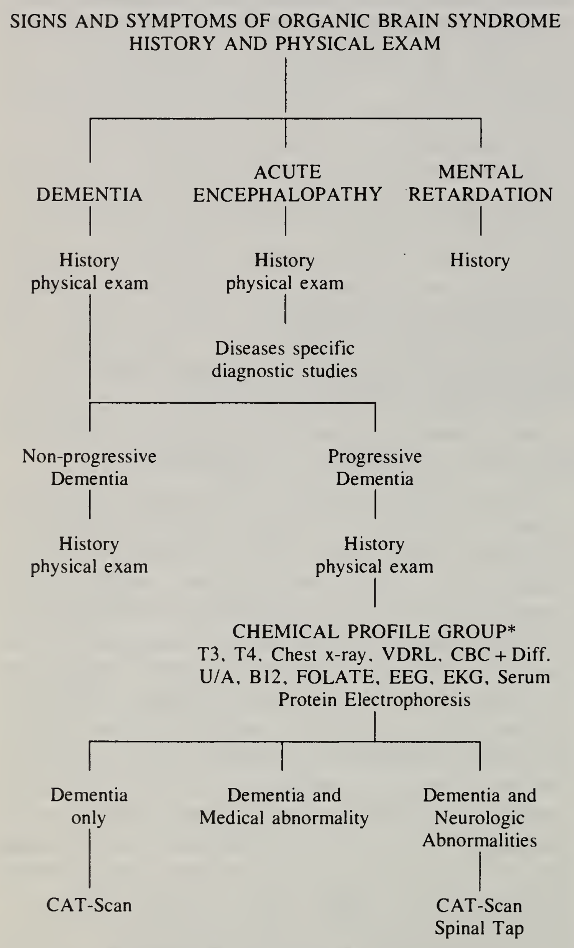
1) disorder of orientation
   (time, person, place),
2) disorder of memory
   (immediate recall, recent memory, remote memory),
3) disorder of intellectual functioning
   (decreased ability to calculate or abstract),

4) disorder of judgment
(decreased logical problem solving of objective situations),

5) emotional lability
(affect can change from minute to minute, i.e., crying, laughing, crying).

A patient can have any or all of these symptoms.

Table 1
FLOW CHART


SIGNS AND SYMPTOMS OF ORGANIC BRAIN SYNDROME
HISTORY AND PHYSICAL EXAM
DEMENTIA
ACUTE ENCEPHALOPATHY
MENTAL RETARDATION
History physical exam
History physical exam
History
Diseases specific diagnostic studies
Non-progressive Dementia
Progressive Dementia
History physical exam
History physical exam
CHEMICAL PROFILE GROUP*
T3, T4, Chest x-ray, VDRL, CBC + Diff. U/A, B12, FOLATE, EEG, EKG, Serum Protein Electrophoresis
Dementia only
Dementia and Medical abnormality
Dementia and Neurologic Abnormalities
CAT-Scan
CAT-Scan Spinal Tap

* Items in Chemical Profile include: glucose, blood urea, nitrogen, total bilirubin, uric acid, ionized calcium, cholesterol, alkaline phosphatase, SGOT, SGPT, lactate dehydrogenase and total protein, creatinine, SED-Rate, potasium, sodium chloride, carbon dioxide.

Once the symptom complex of organic brain syndrome is noted on history and physical exam, differentiation is made between dementia, acute encephalopathy and mental retardation. Mental retardation is best determined by history. Acute encephalopathy presents with a change in level of consciousness. Dementia is usually a sub-acute process without a changing level of consciousness. The dementias are divided into progressive and nonprogressive types.

Nonprogressive dementias usually result from acute encephalopathy such as drug toxicity, metabolic changes, or acute infections. Once the diagnosis and etiology are clear no further evaluation for nonprogressive dementia is necessary unless a progressive dementia is suspected superimposed upon a nonprogressive dementia. For instance, a patient with acute alcoholism and longer-term history of progressing dementia may require evaluation for Alzheimer's type of dementia.

Once the determination is made that the patient has a progressive dementia, it is appropriate to institute laboratory examinations to differentiate among dementia with neurologic abnormalities, dementia with medical abnormalities, and dementia only (see Table 1). B12 and Folate levels are recommended as part of the laboratory evaluation since these deficiencies can cause dementia even in the face of normal peripheral blood smears and red blood cell indices. Serum Protein Electrophoresis is recommended to screen for a silent muliple myeloma.

The dementia plus neurologic abnormalities category, in addition to many other illnesses, also encompasses multi-infarct dementia (arteriosclerosis) and normal pressure hydrocephalus. Only 15% of the elderly with dementia have a true multi-infarct dementia. Normal pressure hydrocephalus is mentioned since it presents classically with a triad of *mild* dementia, ataxia, and urinary incontinence. Alzheimer's type dementia in its further stages can be dementia with neurologic abnormalities but by the time these changes are evident the diagnosis is clear. In the early diagnostic stages when the patient is first seen, Alzheimer's type dementia tends to present as a dementia only.

The primary illnesses one sees in the dementia only category are Pick's Disease, primary degenerative dementia (also called Alzheimer's type dementia and Alzheimer's Disease), major depressive disorder and drug toxicity.

Of all elderly people presenting for dementia evaluation, 65% have irreversible dementias, 50% with primary degenerative (Alzheimer's type) dementia and 15% with multiple-infarct dementia. The remaining 35% have *reversible* dementias with 15% having their illness due to either neurologic or medical abnormalities and 20% having major depressive disorder alone accounting for the presentation of dementia. This latter group is so important to note because they constitute a group that can be quite successfully treated.

It is critical to differentiate major depressive disorder presenting as a pseudodementia secondary to depression from an Alzheimer's type dementia. There is presently no laboratory or psychological test which can achieve this differentiation. It is a diagnosis made by exclusion, and a CT scan of the head is usually part of that diagnostic evaluation to rule out other intracranial pathology. Patients who present with symptoms of dementia only must be considered as possibly suffering from a depressive pseudodementia that may warrant a treatment trial on antidepressant medication. A skilled clinician can at times make an educated diagnosis regarding the presence of pseudodementia. However, the only way at present to determine the presence of pseudodementia is to treat the suspected depression and look for relief of the dementia. It should be noted that patients with primary degenerative dementia are at risk for major depressive disorder and approximately 20% develop major depressive disorder at some time in the course of their illness. This depression superimposed upon a pre-existing dementia at times will worsen the pre-existing dementia. Treatment of the superimposed depression is well warranted and improves the patient's adjustment and function.

Once the diagnostic evaluation is complete, the management of dementia is important to consider. The environment surrounding the demented patient plays the most significant role in managing the patient's behavior. Reality orientation, external anchors, object constancy, and stable emotional tone are the first and most important treatment modalities that should be addressed in patients with behavioral disturbances related to their dementia. A clock, a calendar, and a picture of the family on the bedside table of the patient admitted to the hospital will go a long way toward preventing confusional, paranoid states. A nursing staff approach which explains every procedure and orients the patient to time, person, and place at every possible interaction is also helpful.

Medication and physical restraint are secondary but important interventions when the above interactive approach is insufficient to contain the behavioral problem. It is to be emphasized that psychotropic medication should be prescribed based on the patient's psychiatric diagnosis. The two most common problems that need medication management in the patient with dementia are agitation and depression (discussed above). When prescribing medications for the non-depressed agitated patient there are two broad categories of medication to choose from—the anxiolytics and the neuroleptics. If the patient presents symptoms of psychosis (delusions, hallucinations, paranoia) the neuroleptics in low doses are the medications of choice. The high potency low sedative neuroleptics (haloperidol, thiothixene, trifluoperazine, etc.) have an effective anti-agitation effect without sedation. They unfortunately do cause extrapyramidal side effects in some patients. These side effects can be managed by using as low a dose as possible of the neuroleptic or by adding benztropine, amantadine, or trihexyphenidyl as necessary. If the patient has a non-psychotic agitation, short acting, low dose antianxiety agents are at times helpful (lorazapam, oxazepam, alprazolam, hydroxyzine, etc.). These medications, however, can cause sedation, clouding the sensorium, which is already impaired by the preexisting dementia, leading to increased confusion.

The safest sedative/hypnotics in the elderly are those benzodiazepines that have a short half-life. Secobarbital, glutethimide, and methyprylon should be avoided in the elderly. Short half-life sedative/hypnotics are recommended in order to avoid long-term build-up of sedative side effects leading to increased symptoms of dementia. When using sedative/hypnotics the clinician should be certain that one is not treating a symptom of depression, e.g., sleep disturbance, and thereby failing to address the primary diagnosis of depression.

In summary, it should be noted that the elderly tend to be extremely sensitive to psychotropic medications. Most medications are lipid-soluble, and fat-to-muscle-mass ratios are higher in the elderly. Decreased metobolic rate, decreased absorption rate, decreased elimination rates, and changes in receptor site activity all tend to complicate psychotropic administration. The adage in prescribing psychotropics is:

Go Low,
Go Slow,
But indeed Go.

Physicians should not hesitate to refer a patient for consultation and/or treatment. Geriatric psychiatry is developing as a subspeciality within general psychiatry. A consultant should have a broad-based knowledge of psychopharmacology as well as psychotherapy and should be cognizant of the diagnostic issues involved in differentiating dementia from pseudodementia secondary to depression.

In the elderly, three principles are emphasized: 1) Thoroughness in diagnosis, 2) optimism in approach and 3) persistence in treatment. Most psychiatric illnesses in the elderly can be effectively managed and often cured if properly diagnosed and treated. Nihilism need not apply here.

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Private Psychiatric Hospitals in Connecticut: A Tradition of Excellence, A Future of Change

THOMAS J. CONKLIN, M.D.

No man can tell what the future may bring forth.
—Demosthenes

ABSTRACT—**The six private psychiatric hospitals in Connecticut provide nearly one-third of all psychiatric beds in the state. The traditional role of these institutions has been the long-term treatment of seriously ill patients, but a variety of factors has led to the current trend toward decreased inpatient care and increased ambulatory services. The major forces producing these changes are increased government regulation of health care delivery, escalating health care costs, changing reimbursement practices and more restricted benefits by American businesses. To survive in this changing climate, private psychiatric hospitals must consider fundamental changes in their programs, their methods of operation, and in the patient populations they serve.**

Historical Background of Private Psychiatric Hospitals in Connecticut

The Institute of Living, Hall-Brooke Foundation, Yale Psychiatric Institute, Silver Hill Foundation, Elmcrest Psychiatric Institute, and Natchaug Hospital are Connecticut's six private psychiatric hospitals. They account for 800 of the state's 2800 psychiatric beds, and have a tradition of providing excellent and distinguished inpatient care and treatment. Many also offer professional educational training, outpatient care, and emergency services.[1]

Generally, the role of the private psychiatric hospital has been to treat patients with the most serious mental disorders. A study, conducted by the National Institute of Mental Health and the National Association of Private Psychiatric Hospitals jointly in May 1975, indicated that "three-fourths of patients admitted ...to private psychiatric hospitals ...reported previous psychiatric care."[2] This study suggests that most of the patients admitted pose serious therapeutic problems and many have been previous treatment failures.

In the early 1820's there were only a few hospitals in this country for the treatment of the mentally ill, and in Connecticut there were no hospitals of any kind. The physically ill were cared for in their homes; they might receive the care of physicians licensed by the new Connecticut Medical Society and trained by "riding out" with established physicians or by studying at the Medical Institute of Yale College (1810). The mentally ill remained quietly at home, tended by family members or friends and treated by the family physician. In other circumstances, they might have been locked up, chained, or caged in the absence of other means of control. If indigent and homeless, they were often quietly relocated by town authorities at night to become the responsibility of some other town, a practice commonly known as "bundling." Sometimes the mentally ill were sold at auction and many were thought to be possessed by the devil and were treated as outcasts or persons to be despised.

In May of 1821, Dr. Eli Todd shared with the Connecticut Medical Society his observations on the mentally ill based on his extensive medical practice. He described the plight of the mentally ill in this state in terms so moving, and described the success of the treatment offered at the Retreat Asylum near York, England, in terms so hopeful that the Society immediately established a committee to begin work toward creating such a hospital. The therapeutic approach, "moral treatment," was based on a kind and caring attitude toward the patient while providing a "healthful" and quiet environment. Today's physicians remain comfortable with the concept of moral treatment as explained by Dr. Todd in 1821:

> "Fortunately," said he, "there are certain plain and simple maxims in the moral treatment of the insane which are easily understood and of universal applica-

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THOMAS J. CONKLIN, M.D., Director, Program for Impaired Professionals, The Institute of Living, Hartford, CT, Assistant Professor, University of Connecticut.

> tion. These are to treat them in all cases so far as possible as rational beings. To allow them all the liberty and indulgence compatible with their own safety and that of others. To cherish in them the sentiments of self-respect. To excite an ambition for the good will and esteem of others. To draw out the latent sparks of natural and social affection. To occupy their attention, exercise their judgment and ingenuity and to minister to their self-complacency by engaging them in useful employment altering with amusement"[3]

The hospital was built and received its first patient on April 1, 1824. The Retreat was highly regarded and highly successful from the first and became a model for many other hospitals for the mentally ill that began to appear throughout the country. The hospital was renamed the Institute of Living in 1943. Today, it has 395 inpatient beds and extensive ambulatory care programs, including the Adult Outpatient Clinic, Children's Clinic, an alcohol treatment program, and three day hospitals (adolescent, adult, and geriatric).[4,5] It has had an accredited residency training program in psychiatry for 35 years.

Hall-Brooke, founded in 1889, specializes in long-term care of patients with serious psychiatric disorders, including alcohol or drug abuse. In the mid-1960's, Hall-Brooke Foundation was established as a non-profit hospital, with an inpatient census of 78 beds and a partial hospitalization program.

The Yale Psychiatric Institute was established in the 1930's within the Department of Psychiatry of the Yale Medical School. It offers long-term treatment for adolescents and young adults. It is part of the Yale residency training program, and its clinical and educational programs enjoy a national reputation.

Silver Hill Foundation started in 1931 as an open residential facility for psychiatric inpatients. It became nonprofit and was incorporated as Silver Hill Foundation in 1934. It can accommodate 77 inpatients.

Elmcrest Psychiatric Institute opened in 1938 with 12 patients on an open unit. Today it has 99 beds, a community-oriented partial hospital program, a therapeutic school, a day treatment program for adolescents, and an alcoholism treatment center. National Medical Enterprises became the parent company for Elmcrest in 1982.

Natchaug Hospital started in 1954 as a 40-bed convalescent facility, expanding to 90 beds in 1968. In 1977, it was certified as a non-profit psychiatric facility for adults and adolescents. It provides inpatient psychiatric care, partial hospitalization, alcohol detoxification and rehabilitation, and adolescent services.

Changing Environment

Private psychiatric facilities are undergoing fundamental changes in the health care services they provide. The current trend is toward decreased inpatient care and increased ambulatory services, brought about by increasing regulation, rising health care costs, changing reimbursement patterns and competition for psychiatric services. It is anticipated that both the financing and delivery of psychiatric services will continue to change significantly over the next five to ten years. Dr. John H. Houck, past Psychiatrist-in-Chief at the Institute of Living, pointed out in his Annual Report for 1984:

> "Change is no longer an option for anyone who helps to deliver health care in this country. It is an imperative, more powerful and more urgent than ever in our history. It is driven by social and economic forces, which, having raised costs, demand that they be contained, and, having guaranteed universal access to health care, demand that it be restricted. Those institutions and professional groups which fail to grasp its critical elements in the next decade will, in all likelihood, not be around for a second chance."

The pressures of the market place will pose serious threats for those psychiatric hospitals which continue to adhere to traditional modes of operation and ignore the driving forces of current economic, political, and social trends. The major forces which must be addressed in the 1980's and 90's are:

1. *Government participation and regulation:* The passage of the Medicare and Medicaid laws in the 1960's brought the federal government into direct participation in the medical economy. In turn, Medicare reimbursement was tied to the accreditation and utilization review criteria of the Joint Commission on Accreditation of Hospitals (JCAH). JCAH regulations continue to change frequently, and compliance almost always causes increased expenditures in the areas of personnel, system changes, and documentation requirements.

   Connecticut hospitals are also responsible to another regulatory agency, the Connecticut State Commission on Hospitals and Health Care, created in 1973 and charged with controlling health costs. The Commission reviews the budgets of all general hospitals and the per diem rates for the state's specialty hospitals. The Commission must approve any new clinical programs or capital improvements costing more than $600,000.

2. *Escalating health care costs:* Health care costs have continued to rise significantly since the early 1970's. Total national health care expenditures more than tripled between 1973 and 1983, increasing from $94 billion to $355 billion. Medicare costs alone increased from $4.7 billion in 1967 to $52.2 billion in 1982, and government estimates indicate that those figures will more than double by 1990. There is realistic concern that Medicare will not be solvent after 1994.

3. *Changing reimbursement practices:* In an attempt to curtail rising health care costs, the federal government turned to direct regulation of reimbursement, and, in September 1984, instituted a prospective reimbursement program based on diagnosis-related groups (DRG's) for hospitals certified under Medicare. The DRG system provides a pre-established limit on reimbursement for a medical problem based on diagnostic

classification. Psychiatric hospitals have thus far been exempt from this system, but Congress has instructed the Department of Health and Human Services to include in its 1985 Annual Report an answer to the question of "whether, and the method under which, hospitals not paid under the prospective system can be paid on a prospective basis."[6] In addition private third-party payors also are beginning to limit insurance benefits:

4. *Business and industry:* In 1983, United States companies paid some $80 billion in health insurance premiums, which is more than these companies paid in dividends. American business leaders recognize that the dollars saved from reduced health premiums have a substantial impact on business profits, and they have become much more active in striving to contain the staggering health care costs.

The Effects

This complex and changing environment has been particularly difficult for private psychiatric hospitals which care for patients who often require intensive, specialized, and extended inpatient treatment. Patients who have been treatment failures in general hospital psychiatric units, those who present with difficult or mixed diagnoses, those who need special support services (neuropsychiatric evaluation, intensive care, etc.), and some adolescents with severe ongoing turmoil and chaotic family situations, must have continuous care in a closed, structured environment. An estimated 20% of all hospitalized patients require more than short-term care. Many such patients simply do not do well quickly. Discharge following designated brief periods of hospitalization would be premature and grossly unfair to many of these patients, their families, and the public. Undertreated mental illness is essentially untreated mental illness, and no acronym (DRG, PRO, HMO, etc.) will change that.

The concern of every private psychiatric facility is that changes in reimbursement mechanisms, coupled with stringent regulation, will seriously jeopardize treatment. The impact of prospective payment systems on psychiatric care has the potential to be devastating, especially if the funds allocated are substantially less than the amount needed to treat seriously ill patients successfully. Third-party reimbursement for the long-term inpatient treatment of these patients has steadily eroded. This trend should be carefully noted; it is especially deleterious in psychiatry, and it is discriminatory against the mentally ill.[7]

The Future

Psychiatric hospitals, like all health care facilities, are caught in the dilemma of containing costs while maintaining excellent standards of care. Psychiatric hospitals face the responsibility of continuing their mission of service to the mentally ill, while, at the same time, implementing changes which are efficacious yet cost effective, and, therefore, sustainable in today's environment. The bottom line is shorter lengths of stay for psychiatric inpatients, coupled with higher levels of outpatient and day treatment services.

The bywords for psychiatric hospitals in the near future will be "adaptability," "diversification," and "change." Those who fail to recognize these needs or adjust to them will seriously jeopardize their ability to function and may be forced to merge with more profitable organizations or close their doors.

There are a number of changes which private psychiatric facilities must consider in order to survive in the current health care environment. First, psychiatric hospitals must adjust to today's economic climate by becoming comprehensive mental health treatment systems, offering a full range of psychiatric services, including pre-hospital care (e.g., crisis intervention), specialty units (e.g., adolescent, alcohol and drug, eating disorders, diagnosis, etc.), inpatient services (e.g., brief and acute hospital care, partial hospitalization), aftercare and rehabilitation services. They must be able to offer effective, safe, and beneficial treatment programs in settings that are less costly than hospitalization. Residential settings must vary from crisis units to independent living facilities (supervised apartments, rooming houses). Community and professional education may also be part of this step.

Second, free-standing, private hospitals must consider affiliation agreements, shared services, contract management, or other multihospital arrangements which often can be more effective and efficient in the delivery of services. Today, one out of every three hospitals is affiliated with a multi-institutional system. In five years, it will be every other hospital, and, by the year 2000, the market will be dominated by 25 to 30 "multi-health" corporations. Multi-institutional arrangements vary widely in content and structure, ranging from fairly simple affiliation agreements to complex systems of corporate organization and ownership.[8] For instance, the Institute of Living and Natchaug Hospital belong to the Capitol Area Health Consortium, an organization whose mission is to provide quality and cost-effective care to the patients of its member institutions. Elmcrest Psychiatric Institute is owned and operated by National Medical Enterprises, a private, for-profit, multi-hospital corporation providing technological, financial, and managerial services to that institution. The Institute of Living and Hartford Hospital will operate jointly a 27-bed patient residence at the Institute and crisis intervention services at Hartford Hospital. The operational, treatment, and educational advantages to both institutions are significant, and this cooperative arrangement may well be the first of its kind within the state between a general hospital and a psychiatric institution.

Third, psychiatric hospitals must be responsive to changing forms of psychiatric treatment and alternative reimbursement mechanisms. Key among these are preferred provider organizations (PPO's) and health maintenance organizations (HMO's) in which patient services are offered at a discount in return for a guaranteed large volume of patients. *American Medical News* refers to PPO's as the "hottest ticket in health care, and explosive growth is predicted." There are over 240 PPO's nationwide. It may well be to the advantage of individual or groups of private psychiatric hospitals to offer preferred provider contracts to insurance companies or to specific groups within business and industry.

There are eight HMO's in Connecticut with a total membership exceeding 200,000, or more than six percent of the state's population, and by 1990 that figure may reach 15-20%. In July of 1983, the Institute of Living entered into a contract with Kaiser Permanente to provide the psychiatric services for that HMO population. This unique relationship is among the first in the country between a psychiatric hospital and an HMO. Under the agreement, Kaiser pays a flat monthly "capitation" fee to the Institute, based on the number of Kaiser enrollees (currently 23,000). In return, the Institute provides or supervises all psychiatric services to Kaiser members—outpatient, day treatment, emergency, and inpatient care. The Institute's objectives in this arrangement are to provide psychiatric services in a fiscally responsible fashion and to demonstrate that it is possible under such an arrangement to provide first-class care.[9]

A fourth step for private psychiatric hospitals is to devote sufficient resources to strategic planning and marketing so that they will be prepared for change and able to exercise a favorable influence over future events. Emphasis must be placed on new opportunities and ventures and on management techniques since each is critical to the success, growth, and perhaps even survival of psychiatric facilities. Marketing programs should be oriented to the general public, corporate community, and providers, and these programs should be aimed at enhancing the hospital's image, identifying services provided, and new services that are needed.

Fifth, private psychiatric hospitals must consider corporate restructuring which will allow them to enter into profit-making ventures to strengthen their institutions and provide a still broader array of profitable services. They may well wish to establish or manage nursing homes, home care programs, industrial psychiatry programs, information systems, or other protential, revenue generating operations, including hotel or management services.[8]

Conclusion

One of the dangers of increasing cost containment and regulation, and decreasing reimbursement for psychiatric facilities, is that high quality psychiatric care can be eroded gradually, with the public unaware of the phenomenon until it is too late to recover. The greatest single challenge to Connecticut's private psychiatric hospitals during this current period of transition is to continue to provide the highest quality care to those who need it—within the existing economic and regulatory constraints. Psychiatric hospitals cannot compromise their basic commitment to education, research, service, or superb care and treatment. However, it will be necessary for these hospitals to be flexible and adaptive in response to new opportunities, to develop new ventures as they present themselves, and to move prudently to expand and broaden their services.

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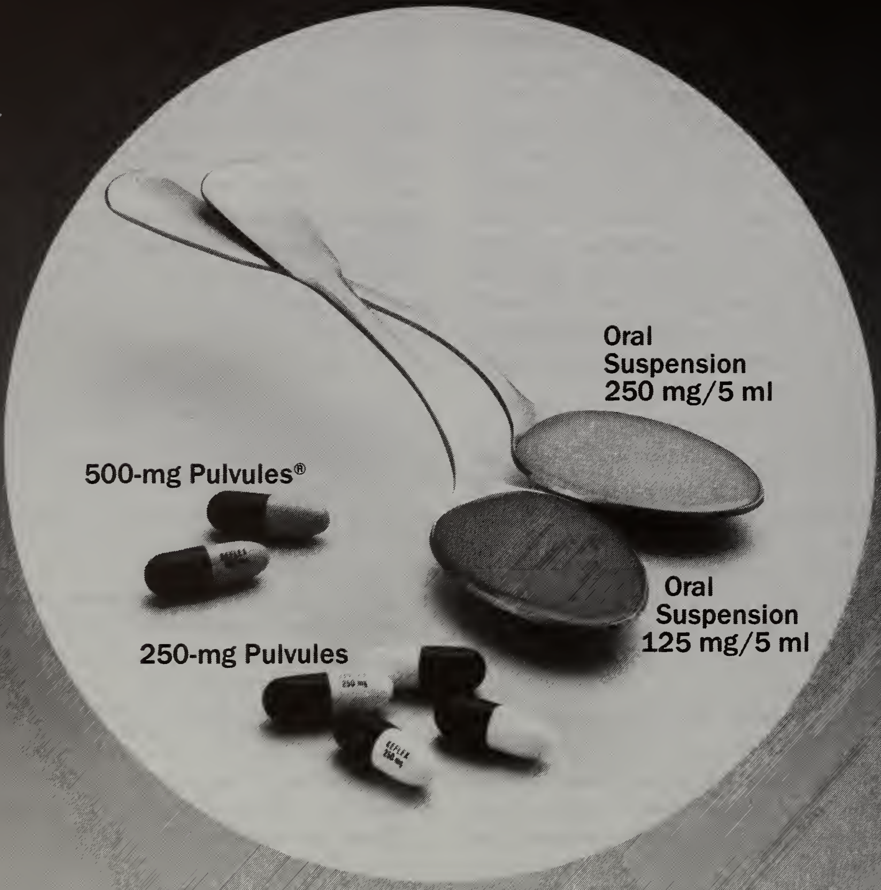

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Important Advances in Clinical Medicine

Epitomes of Progress—Urology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in urology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in urology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Urology of the California Medical Association and the summaries were prepared under its direction.

New Forms of Treatment in Cases of Urinary Stone Disease

Within ten years, medical and surgical treatment of urinary stones has changed radically. Three of the five types of urinary stones, which account for 30% of all stones, may be prevented and, in some cases, dissolved by oral medications. Uric acid and cystine stones will often dissolve with oral administration of alkali and large volumes (more than three liters) of fluids per day. Allopurinol or penicillamine, respectively, will further inhibit formation of these stones. Struvite (magnesium ammonium phosphate) precipitation can be inhibited by giving acetohydroxamic acid or its analogs, and these stones may sometimes be dissolved by irrigating with acid solutions.

Unfortunately, some of the foregoing and the remaining 70% of patients with two types of calcium stones have little hope of dissolving their stones. But we do have many ways of preventing the formation of new calcium stones in such patients: dietary limitation of calcium and oxalate, high water intake and the use of medications such as neutral phosphates, hydrochlorothiazide, citrate and others. A short metabolic evaluation will indicate the best approach for most patients.

For some patients, preventive measures come too late: when they arrive at an emergency room they have nausea, vomiting and renal colic due to stone obstruction. Some will require surgical assistance to be relieved of the stone. In the past, such relief required cutting procedures in more than 70% of patients. Now, only 20% of patients will require "big" operations. In the remainder, stones lodged in the kidney may be pulverized and removed either by percutaneous ultrasonic technique, which requires a puncture in the flank area, or by extracorporeal shock wave lithotripsy, which requires no incision. Ureteral stones, even those near the kidney, may now be pulverized via a miniature telescope with ultrasonic wand, then removed as fragments.

This combination of medical and surgical therapy for urinary stone disease has reduced the stone recurrence rate from 80% to 20%, has reduced the average hospital stay from eight days to four days and the time lost from work to ten days rather than six weeks.

George W. Drach, M.D.
Tucson

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Renal Transplantation

Significant advances have been made in renal transplantation in the past five years. Graft functional survival has risen to between 80% and 90% at one year while patient mortality has fallen to 5% at one year. The best results continue to be achieved with living and related donors. Tissue typing allows the selection of a human-leukocyte-

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antigen-identical sibling donor with a 90% to 95% graft functional result at one year and a 70% graft function at ten years. The use of donor-specific transfusions for recipients of one-haplotype-matched living donor kidneys produces similar highly successful grafts.

Recipients of cadaveric kidneys enjoy an improved graft function with the use of deliberate pretransplant blood transfusions and donor-recipient matching of donor-recipient pairs. These factors will result in 70% graft function at one year. The use of the new immunosuppressant, cyclosporine, can improve this percentage of successful grafts to 80% at one year. The oncogenetic potential of cyclosporine observed in early clinical experience appears to be largely eliminated with smaller dosage schedules.

Pulmonary and other infections were the primary cause for patient mortality in the early decades of clinical renal transplantation. These risks have been reduced such that cardiovascular disease has become the major cause of mortality after renal transplantation.

An increasing number of patients with renal failure due to type I (insulin-dependent) diabetes mellitus are being treated by transplantation with results similar to those reported above.

Donald C. Martin, M.D.
Irvine, California

Section Editor's Comment:

There is still a need for donor kidneys, and local institutions should inquire how they may become a part of this process.

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Endourology

The subspecialty field of endourology has grown tremendously in the past several years. An endourologic procedure is a closed, controlled manipulation within the upper urinary tract; this has become a well-established method of removing upper urinary tract calculi. The advantages of the procedure over conventional open surgical procedures for removing stones are no incision, lower morbidity and a shorter time away from work. Endourology also encompasses other urinary tract procedures such as ureteroscopic stone manipulation, intrarenal operations to relieve obstruction or to do a biopsy of a lesion and stent placement to treat ureteral strictures and fistulae.

Percutaneous removal of renal and ureteral calculi is the most commonly done endourologic procedure. By combining the expertise of a radiologist and a urologist, a nephrostomy tube tract can be established in the collecting system, affording access to specific calyces, renal pelvis or proximal ureter. Once access is obtained, a variety of endoscopic instruments can be used to remove the stone. Smaller stones can be removed intact, whereas larger stones (greater that 1.2 cm) must be disintegrated using either ultrasonic or electrohydraulic energy. Following removal of the stone, the nephrostomy tube is left in for a short period of time (usually one week or less) and on its removal the patient may resume normal physical activity.

To date, we have done more than 300 procedures on a wide variety of surgical calculi, with an overall success rate of greater that 95%. The complication rate has been 4%, with the major complication being hemorrhage to an extent to require a transfusion. In only two cases was an emergency operation necessary to correct complications, and in these cases the end result was good. More than 50% of the procedures are done entirely under local anesthesia and the rest (larger and more complex stones) under general anesthesia. The overall average postoperative hospital stay is three days.

During our initial experience with percutaneous extraction of renal and ureteral calculi, we rejected about 20% of the possible candidates due to various anatomic and technical reasons, in addition to lack of experience. At present, however, virtually all stones that require surgical removal, from simple renal pelvic stones to complex full staghorn calculi, can be removed percutaneously.

Robert I. Kahn, M.D.
San Francisco

Section Editor's Comment:

The author has considerably more experience than many urologists in this procedure. These statistical successes may not always be in that range in the hands of others.

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Magnetic Resonance Imaging and Other Radiologic Advances in Urology

Magnetic resonance (MR) imaging, also called nuclear magnetic resonance, has been in clinical use for about three years. Patients having MR imaging are exposed to a strong magnetic field and radiowaves but no ionizing irradiation. No currently known detrimental biologic effects occur with the magnetic field; however, ferromagnetic objects such as oxygen tanks, poles for holding intravenous fluids or ventilators cannot be placed in the immediate vicinity of the magnet in most MR imaging units. Patients requiring these devices or who are unable to remain quiet for the 45 to 50 minutes required for an average scan cannot be studied. Patients with surgical clips are not a problem but those with aneurysm clips should not be studied due to the possibility of moving the clips.

MR imaging is becoming accepted as the most sensitive imaging modality for many brain and central nervous system lesions. The experience in the pelvis and retroperitoneum is more limited. MR imaging shows better soft tissue contrast resolution than computed tomographic scanning, allowing visualization of the corticomedullary junction in normal kidneys and healthy renal transplants without contrast material. Simple renal cysts can be distinguished from hemorrhagic cysts. Renal masses are easily visualized with about the same resolution as computed tomography. Coronal, sagittal and axial views can be obtained, which are helpful for tumor staging, particularly in the pelvis. Depending on the pulse sequence, MR imaging appears to be more sensitive for detecting abnormalities; however, it has not been specific in differentiating malignant from benign lesions either in the kidney or in the prostate. The procedure has the disadvantage that only large calculi are visualized. MR imaging holds the promise of noninvasively characterizing abnormalities, particularly if any of the MR imaging contrast agents currently being developed prove useful. MR imaging is able to detect blood flow and may be potentially useful for its quantitation. It may be possible with further developments in technology to do in vitro spectroscopy of certain elements, particularly phosphorus.

Several new nonionic contrast agents for urography and angiography are in clinical trials in the United States. One of these,metrizamide (Amipaque, Winthrop Laboratories), is currently available for use in myelography. Studies show that these agents have less hemodynamic, cardiovascular, neurologic, hematologic and renal toxicity and produce fewer unpleasant side effects than currently used ionic agents. They also produce higher urinary iodine concentrations and less diuresis. Whether these agents will reduce the number of serious and fatal contrast reactions in patients having urography is uncertain. When these agents become commercially available, they will probably cost four to ten times more than the currently available agents.

Michael F. Smolin, M.D.
Orange, California

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Treatment of Cancer of the Prostate

Total prostatectomy continues to offer the best disease-free and overall survival in patients with localized prostatic cancer. Patients who undergo total prostatectomy have a significant risk of erectile impotence when a standard radical prostatectomy is done. Those patients who value the capacity for continual sexual activity have been satisfied with a penile prosthesis because the sensation of orgasm is usually intact. In a recent study, Walsh and coworkers suggested modifications during radical retropubic prostatectomy to preserve the pelvic plexus nerves responsible for erections. There is legitimate concern, however, that the less extensive surgical margins and additional dissection required to preserve these nerves might compromise the extent of the operation necessary to remove the cancer.

New concepts and drugs are emerging for treating cases of metastatic prostate cancer. Currently, orchiectomy and diethylstilbestrol are the most commonly used forms of hormonal therapy for managing patients with prostatic cancer. Some patients find the thought of orchiectomy disagreeable, and the use of estrogens is associated with fluid retention and an increased incidence of cardiovascular disease that appears to be dosage related. Luteinizing-hormone-releasing hormones (LH-RH), which appear to obviate these problems, have been synthesized. These drugs actually stimulate testosterone production when initially given; however, ongoing administration has the paradoxic effect of inhibiting pituitary release of luteinizing hormone (and follicle-stimulating hormone), resulting in a fall in serum testosterone to castration levels within two to four weeks. About 50% to 75% of patients have vasomotor hot flashes and most note significantly diminished libido and erectile impotence. Because of the absence of potentially life-threatening side effects sometimes associated with oral estrogen therapy, these compounds might be attractive substitutes.

Antiandrogens have also been evaluated in cases of metastatic prostatic cancer. They may offer an advantage over conventional hormonal therapy in that potency appears to be preserved in most patients. In an effort to prevent disease flare associated with the initial administration of LH-RH, Labrie and colleagues use an antiandrogen at the time of initiating therapy. This combined form of treatment results in "total castration"—that is, it eliminates the effect of any circulating adrenal androgens. A prospective randomized trial to determine whether this combination therapy offers any advantage over conventional therapy is currently being carried out as an intergroup study by several oncology study groups.

The use of chemotherapy for prostate cancer has been studied extensively by the National Prostatic Cancer Project. It is now felt that prostate cancer is heterogeneous and composed of cells that are both sensitive and insensitive to hormones. Hormone "failure" occurs when the hormone-insensitive cells become the predominant cells present. The goal has been to identify single agents and combinations that might prove effective against the hormone-insensitive cell population. The more active single agents that have been identified in randomized trials include methotrexate, cyclophosphamide, cisplatin and estramustine. Trials in which the use of single agents has been compared with that of two- and three-drug combinations have failed to show a statistical advantage of the use of combinations. A variety of combinations have been used, most of which include some sequence of cyclophosphamide, 5-fluorouracil, doxorubicin (adriamycin) hydrochloride, mitomycin, cisplatin or estramustine.

Robert P. Gibbons, M.D.
Seattle

Section Editor's Comment:

External beam x-irradiation and interstitial irradiation are other areas of treatment to be considered in appropriate cases.

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New Uses of Lasers in Urology

The neodymium-yttrium-aluminum-garnet (Nd-YAG), carbon dioxide and argon lasers are now being used for urologic operations. The use of the Nd-YAG laser in the treatment of bladder cancer has offered some unique advantages. The work of Hofstetter in Germany in the late 70s showed a greatly decreased recurrence rate in patients with T_1 and T_2 lesions of the bladder. His 20% recurrence rate in more than 600 patients treated has now been duplicated with a small series by both ourselves and Malloy and co-workers at the University of Pennsylvania.

Other advantages to patients have been a decreased stay in the hospital (generally, the procedure can be done on an outpatient basis or with a one-night stay), usually avoidance of the need for a catheter, ease of treatment of tumors in areas of the bladder not easily accessible with a resectoscope and avoidance of obturator reflex complications. Many patients with carcinoma of the penis, erythroplasia of Queyrat or giant condylomata of Buschke can now also be treated with the YAG laser, avoiding penile amputation. The treatment of small condylomata can be attained with either the CO_2 or YAG laser, but in patients with extremely large, bulky condylomata, the YAG laser has offered a new dimension of treatment that has not been available in the past with conventional means of therapy.

The YAG laser has also been used to treat patients with interstitial cystitis and urethral stricture disease. Patients with interstitial cystitis have shown some promising results, especially those who have been refractive to all other conventional means of therapy. Unfortunately, the treatment of strictures has been the least rewarding of all of the new laser applications due to the relatively high recurrence rate seen by both Smith and ourselves.

A new field that is rapidly developing is the use of dye sensitizers such as hematoporphyrin derivative, which are concentrated in tumor cells and then, when exposed to an argon laser, cause necrosis of the tumor cells. This technique has been used with superficial skin lesions from breast carcinoma or melanoma but more recently has been used in the bladder for treating patients who have carcinoma of the bladder.

As the technology continues to improve, lasers will offer urologists in the 1980s more and exciting applications.

Allan M. Shanberg, M.D.
Long Beach, California

Section Editor's Comment:

Endoscopic laser operation is still investigative in nature and we are eagerly waiting to learn of its full benefits and disadvantages.

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Cancer of Testis Curable

Survival patterns in patients with nonseminomatous germ cell cancer of the testis have shown dramatic improvement in worldwide experience. Management changes in the past seven years have underscored the impact of more effective chemotherapeutic agents along with operative intervention. Using judicious selection of retroperitoneal node dissection and chemotherapy with cisplatin, bleomycin sulfate and vinblastine sulfate, stage B disease is virtually 100% curable. In addition, advanced or relapsed disease responds to salvage chemotherapy with more than 80% survival rates when cytoreductive operations are grossly complete and with 40% survival rates when persistent carcinoma remains.

High inguinal orchiectomy is the universal choice for initial treatment of a testicular tumor. When nonseminomatous tumor is diagnosed, clinical staging includes a computed tomographic scan of chest, mediastinum, abdomen and pelvis for detecting metastasis. Blood tests include determining α-fetoprotein and β-subunit human chorionic gonadotropin serum levels. If staging rules out extensive nodal involvement or widespread metastasis, retroperitoneal lymph node dissection may follow. If all markers are negative for tumor, some centers offer chemotherapy and surveillance alone without doing retroperitoneal lymph node dissection (Figure 1).

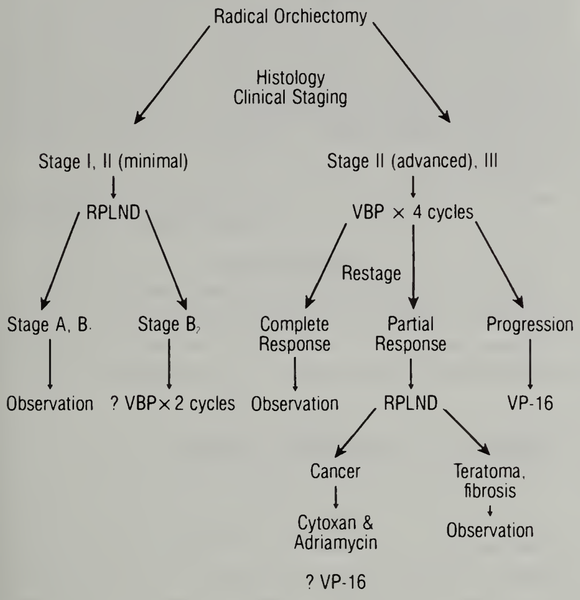

Figure 1
Recommended plan of treatment for patients with non-seminomatous testicular cancer. RPLND = thoracicoabdominal retroperitoneal lymph node dissection; VBP = vinblastine sulfate, bleomycin sulfate and cisplatin; VP-16 = etoposide (VP-16-213).

When no (stage A) or minimal (stage B) tumor deposits are found, close observation with salvage chemotherapy of recurrences (less than 10%) is appropriate. Virtually all such patients with recurrence will respond. When extensive nodal involvement in the abdomen (stage B3) or mediastinum is present or when widely metastatic tumor (stage C) is found, triple-agent chemotherapy is initiated. Patients who respond but who still have residual lesions are subjected to surgical intervention (retroperitoneal lymph node dissection). Patients showing progression may receive adjunctive chemotherapy using other agents such as etoposide (VP-16-213). Combined patient management by a urologist and an oncologist is recommended.

Joseph B. Hart, M.D.
Newport Beach, California

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Needle Urethral-Vesical Suspensions for Stress Incontinence

Since Pereyra first described the needle urethral-vesical suspension procedure for stress incontinence, modifications have provided urologists with a procedure that has a 90% or greater success rate. It eliminates the need for an open pelvic operation through a substantial abdominal incision with splitting of the abdominal wall fascia; it significantly reduces operative time and intraoperative blood loss; it significantly decreases postoperative pain and duration of hospital stay, and it allows repair of an associated cystocele, enterocele or rectocele through the same approach.

The Raz modification of the Pereyra procedure uses a transvaginal approach, passing sutures through the retropubic space with the use of a long blunt needle. These sutures are secured above the rectus fascia, requiring only a small suprapubic skin incision. Transvaginal entrance into the retropubic space completely mobilizes the bladder neck, allowing finger guidance of the needle and the use of endopelvic fascia and posterior vaginal wall substantially lateral to the urethra for the repair. In cases of urethral incompetence due to multiple procedures, a fascial sling underneath the urethra can be constructed using the same approach. This sling will increase urethral closing pressure and provide the needed bladder neck and urethral elevation.

David R. Staskin, M.D.
Shlomo Raz, M.D.
Los Angeles

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Infertility—Evaluation and Management

Andrology is the study of men, particularly the male reproductive system. New developments in recent years have improved andrologists' ability to evaluate, diagnose and treat cases of male infertility. A screening semen analysis is the first step in evaluating a man's fertility potential. This includes the number of sperm, their percentage of mortility and the ratio of normal to abnormal forms. If abnormal, then a medical history and physical examination are in order.

Of men evaluated for infertility, 36% have a varicocele, which is due to abnormal blood flow to the testicle and can be surgically corrected. The technologic advances in microsurgery have increased the success of vasovasostomies, with about 90% having sperm present in the ejaculate. But in only 50% to 70% of cases does a pregnancy result. These differences are probably due to the duration of vas obstruction before vasovasostomy. Structures like the epididymis, which were previously inoperable, can now be readily anastomosed using an operating microscope. An alloplastic spermatocele may provide men with congenital absence of the vas a method of having children; three pregnancies have been reported. In vitro fertilization can also be done to improve fertility when male factors contribute to infertility. This requires only thousands of sperm instead of millions.

In vitro techniques using the husband's sperm can improve the ejaculate for artificial insemination. Artificial insemination with donor sperm is an alternative for those couples in whom the man is sterile and his wife would like to experience the normal sequence of pregnancy, delivery and breast feeding.

The ability to preserve sperm by freezing has revolutionized the clinical treatment of infertility. In the near future, embryo and ovum banks will be as well established as sperm banks are today.

The clinical indications for sperm banking are twofold: one, to preserve sperm for men who will be sterilized either voluntarily by vasectomy or involuntarily due to therapies that will cause irreversible damage to spermatogenesis; two, as a source of donor sperm for those couples who are barren due to male infertility that cannot be corrected. The donors are representative of many backgrounds and offer diverse physical characteristics.

Cappy Miles Rothman, M.D.
Los Angeles

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Noninvasive Evaluation of Scrotal Masses

High-frequency, real-time sonography provides a nonoperative method to locate scrotal masses and to distinguish lesions requiring clinical follow-up alone. Scrotal scanning with 7.5- or 10.0-MHz high-resolution real-time ultrasound correctly identifies vascular, neoplastic, cystic or traumatic lesions of the scrotal contents.

In an infertile patient, a small varicocele may not be clinically detectable. Sonographic detection is superior to that of thermography, venography, radioisotope scanning or Doppler techniques for accuracy. Small varioceles have the same effect on male fertility as large ones and detection defines a therapeutic approach.

Testicular rupture, although rare, is difficult to define clinically due to edema, hematoma and pain. In 30 case studies by sonography, one false-positive and no false-negatives were reported.

Although testicular torsion can be correctly diagnosed with a Doppler stethoscope and radioisotope scans, scrotal ultrasound complements these studies and also defines a nonpalpable testis.

Gray-scale sonography for accurately locating solid scrotal masses at an intratesticular or an extratesticular site has been used for some years. In addition, identification of a clinically occult testicular neoplasm, suspected by biopsy results from a metastatic site, has been reported in several series. At this time, however, scrotal sonography must be considered only confirmatory in the differential diagnosis of benign versus malignant lesions and surgical exploration is required when clinically indicated.

Joseph B. Hart, M.D.
Newport Beach, California

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Advances in Pediatric Urology

The effort of pediatric urologists to identify and correct genitourinary problems at a younger age has been furthered by several recent developments, the most provoking of which is the early diagnosis of fetal anomalies by prenatal ultrasound. Renal agenesis, hypoplasia, hydronephrosis and oligohydramnios may alert a physician to the need for early therapy. If progressive bilateral hydronephrosis with oligohydramnios is found, antenatal intervention percutaneously or via an open surgical procedure or early delivery may be warranted though the risks are high. If the abnormality is unilateral or the amniotic fluid is normal, the pregnancy may be followed to term and further evaluation and treatment undertaken in the neonatal period. This promises improved salvage in the future for problems that might otherwise remain silent until severe renal damage has occurred.

Another less technical advance has been the growing appreciation for the need to thoroughly evaluate the first childhood urinary tract infection, regardless of the sex of the child. Most renal scarring from pyelonephritis has occurred by age 4 years. Before that age, immature renal papillae may contribute to intrarenal reflux, which, combined with vesicoureteral reflux of infected urine, may transform cystitis into pyelonephritis. Because a single childhood urinary tract infection has an 80% chance of recurrence, and voiding cystourethrography done on white children for infection shows reflux in 29% to 50%, the best approach to preventing recurrent pyelonephritis with its complications of hypertension, proteinuria and reduced renal function is to properly document all instances of urinary tract infection and do a diagnostic workup on those children after the first such episode.

Voiding cystourethrography or isotope cystography and excretory urography or renal ultrasound studies usually are sufficient to identify upper urinary tract anomalies, obstruction or reflux; cystoscopy is reserved for selected situations. Analysis of urine and urine culture should be considered in evaluating all febrile childhood illnesses, however transient. The goal is to identify and correct contributing causes to upper urinary tract infection and thus prevent progressive morbidity and renal damage.

On the surgical front, the impetus has been to earlier surgical procedures, often done on an outpatient basis. Electron-microscopic studies of patients with undescended testes showing deterioration beginning by age 1 year have indicated that the optimal age for orchidopexy be revised down to age 12 to 24 months. While studies evaluating the proper role for human chorionic gonadotropin or gonadotropin-releasing hormone in treating this condition are not yet complete, this hormonal manipulation should be begun by age 18 months, allowing early orchidopexy if it fails. The early promise of the gonadotropin-releasing hormone in European trials has not yet been confirmed here.

The most common type of hypospadias, a subcoronal meatus with an incomplete, dorsal-hooded foreskin, is now best treated by the meatoplasty and glanuloplasty ("MAGPI") procedure as introduced by Duckett. With advancement of the meatus onto the glans and repositioning or revising the foreskin, the procedure can easily effect an excellent cosmetic result with few complications. Often it can be done on an outpatient basis and be completed in infancy. Such procedures and timing should prevent the emotional and sexual insecurities that often accompany genital deformities in older boys.

Jeffrey Kaufman, M.D.
Santa Ana, California

Section Editor's Comment:

The appropriateness of antenatal intervention is being investigated.

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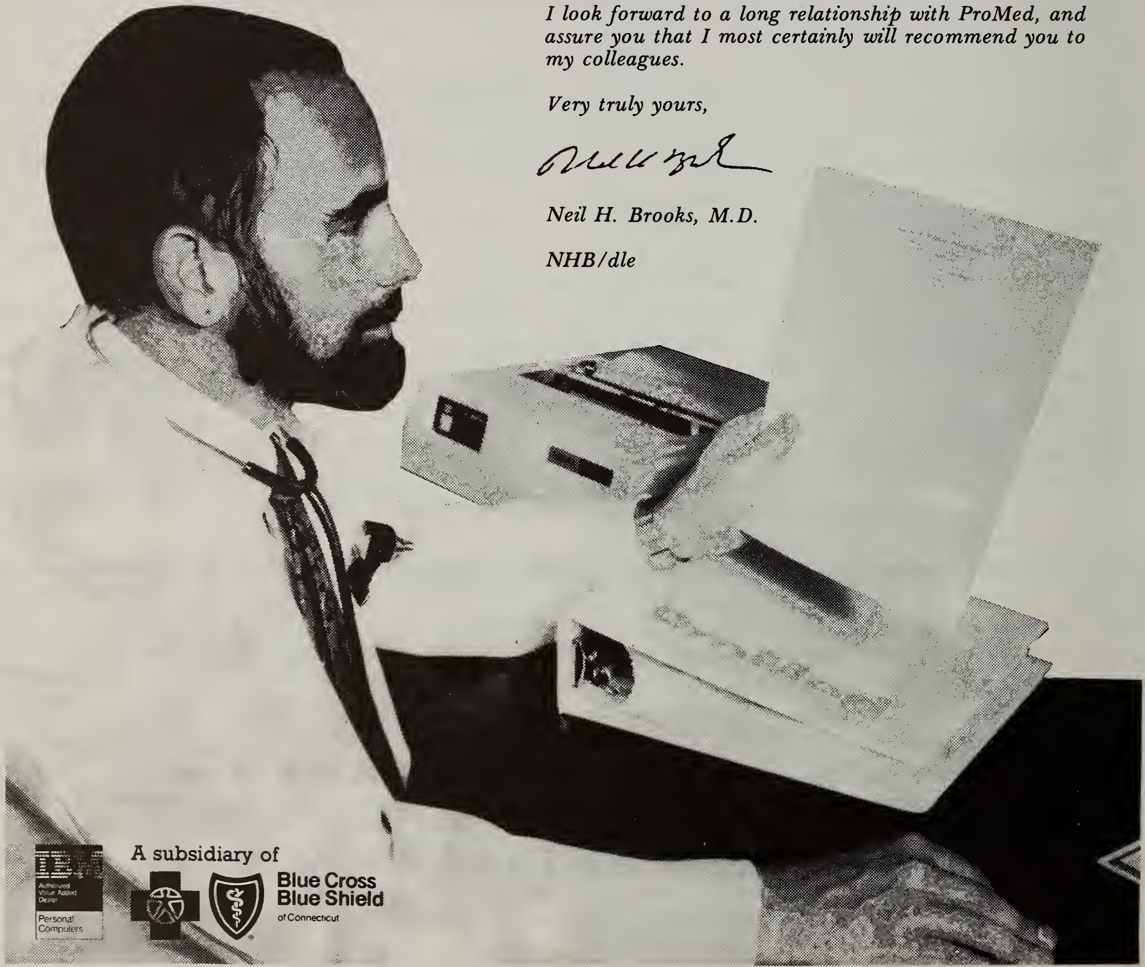

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Current Developments in the Law: Malpractice and Informed Consent

J. MICHAEL EISNER, ESQ.

An Historical Perspective

The incidence of malpractice suits has reached very significant proportions, and a number of extraordinarily high judgments have attracted widespread attention.

Curiously, there were no significant number of malpractice suits until the 1930's. There was a marked decline in suits during the Second World War, but after the war the number of suits began increasing rapidly.

By 1983, among 196,000 insured physicians in the United States, 32,000 claims were made alleging malpractice.

The highest incidence of suits was in the northeast.

According to St. Paul Insurance Company, a major professional liability insurer, the five leading allegations in its 1983 claims were as follows:

1. bad results;
2. falls;
3. treatment delays or omissions;
4. injuries to body parts adjacent to the treatment site; and
5. wrong diagnoses.

The average paid loss in 1983 sustained by 23 physician-owned insurance companies was $72,000 per case.

The highest average payout involved cases involving injuries to infants.

California statistics indicate that the percentage of verdicts for plaintiffs is running approximately one out of three, with 68% of the 1983 California verdicts being for the defendant physicians and hospitals.

The cost of malpractice insurance also has been increasing dramatically. Hospitals, which traditionally had low premiums, have sustained enormous increases in premiums as evidenced by our experience in Connecticut. This year alone, Connecticut hospitals will spend approximately $20 million for malpractice insurance, and they expect this cost to increase significantly in the future.

What Has Caused the Malpractice Crisis?

What are the reasons for this situation?

According to the Presidential Commission on Medical Malpractice appointed by President Nixon which reported in 1973, not the least of the reasons is the problem of rising expectations. According to the Commission,

> *The press and broadcasting media fostered greater public interest in medicine and particularly in its "miracles", leading the public to develop many unrealistic expectations about medicine's capabilities. Many Americans regard good health as though it were a commodity, something that the doctor can dispense at will. But good health is not a purchasable commodity. It is a matter first of heredity and, above all, a matter of personal responsibility, choice, and self-governance. Unfortunately, the failure to achieve ideal health has caused great disappointment with the results of treatment on the part of some patients and they have turned with greater and greater frequency to the lawsuit as a means of resolving their disappointment.*

Another reason which has been cited is the new and increased risks of injury associated with new and more potent drugs and more sophisticated medical techniques such as, for example, heart transplantation.

A case in point is *Karp v. Cooley*, a 1974 case involving the prominent surgeon Denton Cooley. The case involved a heart transplantation in 1969 when Dr. Cooley implanted the first totally mechanical heart in 47-year-old Mr. Karp. Mr. Karp died and his wife brought a wrongful death action against Dr. Cooley.

The gist of the Karp complaint was that Dr. Cooley did not inform the Karps that heart transplantation was risky business!

After a lengthy trial and appellate proceeding, the court concluded that indeed there had been informed consent to the procedure.

J. MICHAEL EISNER, ESQ., Partner in the Law Firm of Wiggin & Dana, New Haven, CT.

As long ago as 1932, a prominent treatise on torts, by chance named Cooley, offered the following view:

> *It is the misfortune of members of the learned professions that, in a very considerable proportion of all the cases in which their services are employed, their efforts must necessarily fall short of accomplishing the purpose desired, so that if they do not disappoint expectations, they must at least fail to fulfill hopes. For this reason they are peculiarly liable to the charge of failure in the performance of professional duty, and it is therefore important to know exactly what it is that the professional man promises when he engages his services.*

In addition, the increase in actions for malpractice and failure to obtain informed consent perhaps reflects a widespread desire in our increasingly complex and bureaucratic society for more individual freedom, for more control by the individual. At the same time as malpractice suits were increasing, we witnessed the rise of the civil rights movement, the creation by the Supreme Court of a constitutional right of privacy, and various student movements.

Thus, when sophisticated procedures fail, or when the art of medicine proves imperfect and physician fail to cure or make mistakes in spite of widely publicized advances in diagnostic techniques, disappointed patients and members of their families increasingly have sought redress through the courts.

Changes in the Law

Accompanying the increase in lawsuits, there have been some significant changes in the law.

The demise of the locality rule

At one time, a physician was only held up to the standard of practice in his community, the so-called "locality" rule. Cooley wrote in 1932 that:

> *Locality is to be taken into account and the physician in a small and remote community is not to be judged by standards which obtain in the great centers of population. The rule is that he must exercise that degree of care and skill ordinarily exercised by the professsion in his own and in similar localities.*

This rule no longer exists in Connecticut.

In 1932, the Connecticut Supreme Court in the case of *Geraty v. Kauffman* rejected the locality rule, and held that the standard of care in Connecticut shall be the same for the entire state. Thus, a surgeon in a rural hospital such as Day Kimball will be held to the same standard as a surgeon at a large urban hospital such as Yale-New Haven.

In 1983, in the case of *Logan v. Greenwich Hospital*, the Supreme Court of Connecticut held that the standard would be a national standard. The Court explained its position as follows:

> *We think the time has come to broaden the geographical limitation we have previously imposed to include the entire nation. Under contemporary conditions there is little reason to retain this vestige of former times when there was a substantial basis for believing "that the rural doctor should not be held to the standards of the urban doctor, since the latter had greater access to new theories and had more opportunity to refine his method of practice."... We are not aware of any differences in the educational background and training of physicians practicing in Connecticut compared with those in other states. Medical literature of significance is normally disseminated throughout this country and not confined to a particular state. We align ourselves with many other jurisdictions which have in recent years abandoned similar geographical restrictions in medical malpractice cases.*

Erosion of the Statute of Limitations

More recently, our courts have begun to question the wisdom of our statute of limitations. The statute of limitations for actions involving professional liability in Connecticut, Section 52-584 of our General Statutes, has provided for a number of years that an action must be brought within two years from the date when the injury is first sustained or discovered or in the exercise of reasonable care should have been discovered, except that no action may be brought more than three years from the date of the act or omission complained of. In other words, even if the malpractice was not obvious or could not reasonably have been discovered, an action more than three years from the date of the alleged malpractice is barred.

In the case of *Puro v. Henry*, decided in 1982, the Connecticut Supreme Court held that if there were evidence of fraudulent concealment of the malpractice, the three-year statute of limitations would be tolled, meaning that the plaintiff could get his claim to the jury. Judge Shea in his dissent said that:

> *I am concerned not only about this case, which I concede as a 'hard' one, but also about the ramifications of the majority opinion in rendering the protection afforded by the statute of limitations largely illusory in malpractice actions and perhaps in others. In virtually every case the wrongful conduct is susceptible of two possible explanations: (1) that it was inadvertent and (2) that it was intentional at least in the sense that the defendant was aware of his error and failed to reveal it. The majority would give the jury complete freedom to choose the second alternative without any indication from the evidence that the case presented a rare occasion of villainy rather than a common instance of negligence. This deference to the trier leaves virtually any professional exposed permanently to a claim that he had actual knowledge of his misconduct when it occurred and that, by failing to disclose it, he is guilty of fraudulent concealment which removes the statutory bar.*

This year, in the case of McDonald v. Haynes Medical

Lab, a Superior Court Judge held the three-year statute of limitations unconstitutional. He said that the statute does not give the plaintiff enough time to discover the injury.

In his opinion, the Judge cited a recent Arizona case, *Kenyon v. Hanmer*, which had reached the same result.

However, a recent case in the Tenth Federal Circuit Court of Appeals, *Brubaker v. Cavanaugh*, reached the opposite conclusion and held that a similar statute of limitations in Kansas was constitutionally acceptable.

If the *McDonald* decision is sustained by the Supreme Court of Connecticut, the door would be opened for the filing of very old claims. For example, it would be possible for a plaintiff to claim that some action of a physician ten or twenty years ago resulted in damage and was actionable at this time.

This year, a bill was introduced into the Judiciary Committee of the Connecticut General Assembly which would have eliminated the three-year statute of limitations. It died in that Committee on April 23, but it is likely that it wil be brought up again in the future.

If the three-year statute of limitations is repealed, then physicians not only will face potential liability going back for many years, but if they have insurance policies which are written on a claims-made basis (in other words, policies which cover them only for claims made during the term of the policy), they will be required to purchase so-called "tail" insurance when they retire or cease practice since they will be exposed to potential malpractice claims for a number of years.

Developments in Damage Awards

Recently, the Connecticut Supreme Court decided another case, *Peck v. Jaquemin*, which promises to further increase damages awarded in malpractice cases. The court held that under Section 52-216a of the Connecticut General Statutes compensation already received from other tortfeasors is to be ignored by the judge and treated as a bonus in addition to the fair and reasonable award for the damages sustained as determined by the jury unless the judge determines that the total amount of the plaintiff's recoveries are excessive as a matter of law. The well-established common law rule that an adequate award of damages must be reduced by payments received from other tortfeasors involved in the same incident was destroyed by the Court's reading of § 52-216a. It is pointed out by Judge Shea in his concurring opinion that the majority's ruling

> *creates the anomaly that plaintiffs who are fortunate enough to be damaged by several tortfeasors, as in a multiple-car accident, may recover compensation for the same damages against each of several tortfeasors in a succession of settlements until the ceiling of excessiveness as a matter of law is reached.*

Judge Shea argues that

> *. . . [t]he amount received . . . should be deducted by the court from the jury determination of reasonable damages for the injuries sustained, unless this deduction would render the total compensation of the plaintiff inadequate as a matter of law.*

New Causes of Action: The Duty to Warn

In recent years, courts across the country have created new causes of action which can be brought against physicians and hospitals.

The most well-known of these new causes of action is the duty imposed on psychiatrists to warn third persons that their patients are potentially dangerous. In the well-known *Tarasoff* case, the Supreme Court of California held that a psychiatrist had a duty to warn third persons if his patient represented a threat to an identified target. In that case, the psychiatrists were treating a patient who had threatened a specific girl. The patient refused treatment, and then sometime later killed the girl. Although no duty had existed on the part of physicians to warn third persons in such circumstances, the Supreme Court of California created such a duty.

A number of courts in other states have followed the *Tarasoff* decision, although to date there has been no case in Connecticut.

Furthermore, in several recent cases the duty has been extended in some jurisdictions to include liability for acts of potentially dangerous patients, even though they have not threatened any particular person. In one case, for example, an individual with dangerous proclivities shot people in a nightclub. In another case, a psychotic driver killed someone in a car accident. In both cases, the courts held that the psychiatrist was under a duty to warn. Recently, however, in the case of *Brady v. Hopper*, an action by Jim Brady against Hinckley's psychiatrist, the federal Court of Appeals for the Tenth Circuit rejected this theory.

The obvious problem in these cases is that if the psychiatrist makes a mistake, he has breached confidentiality, and is liable to the patient for any damages flowing from that breach of confidentiality. The psychiatrist thereby may well be placed in an untenable position.

One can only speculate about potential new causes of action or theories of liability. For example, what if a small hospital does not have a CT scanner, but yet runs an emergency service. Everyone knows that CT scanning is the state-of-the-art diagnostic technique for head injuries. What if a patient comes to your small hospital and you cannot perform a CT scan? Are the hospital and its physicians negligent because they do not have a scanner? The answer very possibly is yes.

Developments in the Law of Informed Consent

There also has been a rapid development in the law of informed consent. Although cases on informed consent began to appear approximately 65 years ago, the frequency of such claims has increased substantially during the last 25 years.

The traditional rule in these cases was that a physician must give the patient such information as commonly would be provided by a practitioner to his patients in the particular locality.

In 1972, however, in the landmark case of *Canterbury v. Spence,* a new theory was adopted to the effect that consent should be reviewed through the eyes of the patient rather than the physician. In this case, a 19-year-old plaintiff with a history of back trouble consulted the defendant physician, who advised a laminectomy. During the course of the operation serious spinal difficulties were found and the plaintiff eventually was paralyzed. The plaintiff claimed both negligence and lack of informed consent. A jury verdict in favor of the defendant physician was reversed on the issue of informed consent. The plaintiff had testified that the defendant physician did not disclose any specific risks to him. The plaintiff's mother testified that the defendant had told her that the operation was no more dangerous than any other. The defendant admitted that there was a one percent risk of paralysis but that according to his best surgical judgment this fact should not have been revealed. It was on this point that the appellate court reversed. The court said that the duty to disclose depends on what information is necessary to permit the patient to make an informed decision. A one percent risk of paralysis may be within such limit. The burden is on the patient to show that a reasonable doctor would have disclosed such risk and that a reasonable patient upon being informed of such risk would not have consented to the operation. The case was sent back for a retrial on this issue.

The *Canterbury* rule has developed into the familiar formulation of consent that the physician must disclose:

1. the nature of the procedure;
2. the risks involved in the procedure;
3. any alternatives to the procedure; and
4. the potential benefits of the procedure.

The Connecticut Public Health Code requires hospitals to provide in their medical staff bylaws or rules and regulations that physicians obtain informed consent under this standard.

In 1983, in the *Logan* case, discussed above, invovlving the total demise of the locality rule in Connecticut, our Supreme Court adopted the *Canterbury* rule to be applied in Connecticut.

Physician Respsonsibility

We also must all keep in mind the fact that a significant number of patients are the victims of clear malpractice.

In addition, there are a number of physicians who are impaired because of alcohol and drug addiction and physical disability who should not be practicing.

Our Medical Examining Board in recent years has seen physicians who have committed such acts as deliberately implanting pacemakers in patients who clearly do not need the pacemakers, selling drugs to addicts, sexually abusing patients, and otherwise abusing their licenses to practice and their medical oaths.

Barring incompetent physicians from practicing would contribute significantly to solving the problem. A study by the Florida Insurance Commissioner concluded that from 1975 through 1982, 7/10 of one percent of Florida physicians were responsible for 24% of the claims in which indemnity payments were made. A California study similarly concluded that 6/10 of one percent of Los Angeles area physicians accounted for 30% of all payouts.

Until recently, medical staffs often were reluctant to remove the medical staff membership or clinical privileges of a colleague usually for reasons of sympathy and desire not to destroy the colleague's livelihood even though he should not be practicing or his practice should be severely limited.

Even today, when a hospital removes a physician from its staff, he often is allowed by the state to continue to paractice in the community.

There are also situations which arise from time to time such as the infamous situation in California in which a surgeon admitted that he had performed numerous unsuccessful laminectomies, leaving literally scores of patients crippled, because he needed money from these operations to support his drug habit. He admitted that he lacked the skill to competently perform these procedures.

Obviously, people who suffer injury as a result of genuine malpractice deserve reasonable access to the judicial system and fair and reasonable levels of compensation for their injuries.

The Role of Attorneys

The legal profession serves as the gatekeeper in regard to malpractice litigation, and has an obligation to act responsibly on behalf of its clients. As pointed out over a decade ago by a member of the Connecticut Bar, there

> *is thrust upon the lawyer a serious obligation to sift the wheat from the chaff, when consulted by a client interested in pressing a claim for malpractice. In a sense, the attorney's office is the first bastion of justice, for it is he who must at once protect the public by pursuing claims of merit, while preserving the honor of the medical profession by discouraging those of idle worth. He must choose carefully, disregarding notions of inter-professional antagonism on the one hand, and professional camaraderie on the other. And yet, such is not an easy task, for no other confrontation in law is fraught with as much emotion.*

Unfortunately, the Bar has not always lived up to this responsibility and some attorneys have pressed claims of dubious merit.

Members of the Bar should face up to their responsibility to see that the system works properly.

Possible Solutions: Legislative Proposals

What then are the possible solutions to this problem?

First of all, medical societies, hospital associations, and groups of hospitals have established their own insurance companies. These so-called "captive" insurance companies are becoming more common. Hopefully, through such companies, physicians and hospitals may lower their premiums by eliminating the profit factor enjoyed by the private companies. Because of the acceptance by state departments of insurance of the use of arcane accounting procedures, insurance companies are not required to reveal their actual profits which often may be very significant.

A second major solution is better risk management. Hospitals across the country have adopted risk management programs to provide continuing education to their physicians in regard to issues such as informed consent, and to attempt to reduce risks through better administrative policies and through removing unfit physicians.

The special task force on professional liability and insurance of the American Medical Association issued a report in October of 1984, setting forth a number of its proposals to deal with these problems. Among them were the following:

1. to limit noneconomic damages available to a plaintiff;
2. to eliminate punitive damages;
3. to cause verdicts to be itemized;
4. to structure settlements;
5. to establish maximum awards and to create patient compensation funds for awards in special circumstances which may exceed the statutory limit;
6. to elimimate the collateral source rule; in other words, to permit the jury to know about the availability to the plaintiff of compensation from other sources;
7. to restrict contingency fees;
8. to establish pretrial screening panels;
9. to establish standards for expert witnesses;
10. to modify statutes of limitations;
11. to permit affidavits of noninvolvement to be filed by persons who are named in the lawsuit but who are not involved at all, and then to permit these people to be excused from the case after preliminary hearing by the court;
12. to establish penalties for frivolous lawsuits;
13. to encourage the binding voluntary arbitration of claims;
14. to improve risk management in a number of ways; and
15. to strengthen state licensing boards so that they may remove the licenses of marginal practitioners.

In Connecticut, three bills were introduced into the General Assembly this year pursuing various of these ideas. One Medical Society bill would have prohibited lump sum payments to successful plaintiffs. A second bill, sponsored by the Connecticut Hospital Association, would have made medical malpractice screening panels mandatory, permitting findings in regard to liability by such panels to be admissible into evidence. The third bill, sponsored by the Medical Society and supported by the Hospital Association, would admit collateral source payments into evidence. This latter bill in its original form would provide that:

> *In any action for malpractice, error or omission against a health care provider for the recovery of damages for personal injury or death, any fact available as to all sums paid or payable to the plaintiff shall be admissible in evidence.*

The experience of other states in regard to such legislation is instructive. The following summary is based on a tabulation prepared in 1984 by the American Medical Association's Division of Legislative Services:

> *In regard to limitation on fees, eighteen states have statutes in force, in two states such statutes have been found constitutional, in two states such statutes have been found unconstitutional, and in two states, Rhode Island and Idaho, such statutes have been repealed.*
>
> *With regard to the collateral source type of legislation, eleven states presently have statutes on the books. In four states, such statutes have been found constitutional, in three states such statutes have been found unconstitutional, and in one state they have been repealed.*
>
> *With respect to limits on liability, ten states presently have such legislation. In two states, it has been found constitutional, in four states it has been found unconstitutional, and in one state it has been repealed.*
>
> *With respect to periodic payment legislation, thirteen states have statutes on their books. In two states, such statutes have been found constitutional, and in two states they have been found unconstitutional.*

Recently, in the case of *Roa v. Lodi Medical Group*, decided on February 7, 1985, by the Supreme Court of California, the California statute limiting contingency fees was found constitutional and survived claims that it violated due process, equal protection, and the separation of powers.

The California statute provides that in regard to contingency fees an attorney may recover 40% of the first $50,000, one-third of the next $50,000, 25% of the next $100,000, and 10% of everything over $200,000.

There was a strong dissent in the *Lodi* case by Chief Justice Bird who said that the decision would place a heavy and impermissible burden on plaintiffs in obtaining adequate legal representation.

Conclusion

In closing, I would like to share with you a column written by Art Buchwald several years ago which takes a less anguished view of the problem but yet squarely presents it to us.

The subject matter of this column was "Defensive Medicine":

One of the reasons medical costs are soaring, according to a physician I know, is that doctors are now practicing "defensive medicine."

"The reason for 'defensive medicine' is that for every doctor practicing in this country, there are now two lawyers waiting to sue him for malpractice," said my friend Dr. Gingseng.

"How do you practice defense medicine?" I asked.

The M.D. said, "Suppose you come to see me with swollen tonsils. The first thing I would do is order an X-ray of your stomach."

"Because?"

"In case I want to take your tonsils out I must make sure I'm not sued for giving you ulcers."

"That's only good medical practice."

"Then I have to order blood tests to protect myself in case you had malaria or yellow fever."

"Are swollen tonsils an indication of malaria or yellow fever?"

"It's highly unlikely, but your lawyers could always find a doctor who will say they are. After the blood tests I might order a brain scan."

"Why a brain scan?"

"Just as precaution in case you tried to claim that after I took out your tonsils you lost your memory. Of course I would also have to give you an EKG and a stress test, so they couldn't get me for causing any heart damage."

"What else would you have to do to protect yourself?"

"After all the tests, I would make you sign a paper saying that you agreed to my decision to remove your tonsils. Of course I would prefer you get a second opinion from another doctor, because that would bolster my defense that you had to have them out."

"Okay, I've signed all the papers. Now will you take my tonsils out?"

"My insurance company would prefer I talk to another member of the immediate family. Many times the patient is willing to go along with the operation, but the rest of the family prefers to sue. After all it isn't their tonsils that are swollen."

"I'm sure my wife isn't that type. If you say my tonsils have to go, she'll go along with your decision."

"I'd rather have it from her in writing."

MEDICAL SOCIETY MEMBERSHIP COSTS: STILL GOING UP

Between 1979 and 1985, the cost of belonging to a state medical society increased an average of $64 and now ranges from $150 in Missouri to $490 in Hawaii. Doctors in Washington, D.C., pay the highest of all, $585.

What doctors pay their medical societies

Ala.	$175	La.	$235	Ohio	$250
Alaska	350	Maine	330	Okla.	210
Ariz.	300	Md.	250	Ore.	300
Ark.	225	Mass.	270	Pa.	275
Calif.	310	Mich.	290	R.I.	300
Colo.	380	Minn.	375	S.C.	220
Conn.	175	Miss.	235	S.D.	300
Del.	205	Mo.	150	Tenn.	170
Fla.	225	Mont.	370	Texas	235
Ga.	300	Neb.	265	Utah	285
Hawaii	490	Nev.	180	Vt.	200
Idaho	370	N.H.	225	Va.	195
Ill.	253	N.J.	275	Wash.	298
Ind.	235	N.M.	250	W.Va.	250
Iowa	300	N.Y.	225	Wis.	455
Kan.	220	N.C.	190	Wyo.	300
Ky.	300	N.D.	250		

Source: State medical societies.

—MEDICAL ECONOMICS, July 22, 1985

Computers in Hospital Management: Patients, Doctors, Information and Resources

ROBERT T. SADOCK, M.D.

Overview

The computer revolution has arrived. If the airline industry had progressed as rapidly as the computer industry over the last 25 years, the cost of a Boeing 767 would be $500. It would travel around the world in 20 minutes on five gallons of gasoline. There has been a 25% per year decrease in the cost computer logic devices and a 40% reduction yearly in computer memory. The power required to run computers has decreased by over 10,000 times.

Along with the rise of the computer industry, there has been a concomitant change in office automation. Computers aid in word processing and the building of data bases to assist secretaries and office managers. Electronic mail is in frequent use in many institutions. Computers are also used in the workplace for training purposes. They can interactively display information and ask questions for the user to respond to. Various devices can be used to combine video tape recorder technology with the computer.

Several additional capabilities are currently in their infancy but about to make a major impact on the operations of an office. A device can be bought for a personal computer that will understand and carry out over 200 voice activated commands. Another device costing under $500 can read most typewritten material and transfer the letters into a computer. Black and white pictures can currently be stored in the computer and soon there will be mass storage devices available for capturing thousands of color pictures.

The Rise of Hospital Computer Systems

Prior to 1984, Yale-New Haven Hospital had six different computer data bases that were actively used. These included:

1. Patient Admitting Information
2. Clinical Laboratories
3. Patient Billing
4. Patient Care Evaluation—a data base to aid in the analysis of utilization of hospital resources.
5. Pharmacy
6. Radiation Therapy

Over the past 14 months, there have been an additional 10 data bases added to the prior six. These include:

1. Clinical Assessment Task Force—used to analyze hospital resources by physician and patient groupings.
2. Crit-Calc—used to calculate complex cardiac and respiratory values including cardiac output.
3. Diagnostic Imaging
4. Financial Analysis—used to analyze hospital profit and loss by DRG, insurance type and physician.
5. Medical Staff Office—used to keep track of members of the Medical Staff including information for complying with the JCAH and Medical Staff Bylaws.
6. Operating Room—used to record operating procedures, the surgeons and nurses who perform them, and several quality assurance variables.
7. Pathology—used to track and report biopsy specimens.
8. PCSS—a clinical information system being developed for ordering, charging, and results reporting for all hospital tests and procedures.
9. Physical Therapy—used to evaluate physical therapy procedures by DRG.
10. Risk Management—a system being developed to track incident reports, potential malpractice cases, and identify high risk activities.

ROBERT T. SADOCK, M.D., Physician Administrative Associate, Yale New Haven Hospital, New Haven, CT.

This paper was presented at the 193rd Annual Meeting of the Connecticut State Medical Society, May 9, 1985.

In order to gain some insight into some of these computer data bases, three examples will be explained in more detail.

The Medical Staff Office Data Base

Yale-New Haven Hospital has approximately 1,900 physicians on its Medical Staff. There is a relatively high turnover of several groups of physicians including house staff and fellows.

The JCAH and Medical Staff Bylaws require that a surveillance function take place with regard to ensuring that each physician has proper malpractice insurance, a valid license, continuing medical education activities and has no health condition that could affect his or her professional competence.

In order to keep track of all these variables, as well as demographic and communications information, it was necessary to purchase and program an IBM personal computer. A questionnaire was distributed to each member of the Medical Staff asking them about many of the above variables. This information was entered into the computer over the next several months. The Medical Staff Office then cross-tabulated this information with lists from the State of Connecticut, the Admitting Office, and various other departments in order to cross-check the accuracy of the information given.

There were several interesting results from this process. First, there was a better understanding of who the Medical Staff is at Yale-New Haven Hospital. Our staff is composed of University and Community based physicians as well as individuals in many different categories including house staff, fellows and affiliated professionals. The Department of Medicine, for instance, has 520 members; 226 University-based and 294 Community-based.

Admitting privileges were much more clearly delineated and this information was passed to the Admitting Office to ensure that patients were admitted appropriately.

The computer system allows the Medical Staff to remind physicians that they must send in the annual fee to maintain a valid license. It also allows the office to follow-up on those physicians who do not follow this procedure.

The Medical Staff Office also received information regarding physician certification. Many physicians, since first coming on Staff at the Hospital had not told the Medical Staff Office that they had been certified in a specialty or sub-specialty area.

With regard to the JCAH question on any health condition that might impair professional competence, aside from the occasional response of being "overworked," we learned that our medical staff is in excellent health.

Patient Care Evaluation Computer System

Using information from the Admitting Office, Billing, Clinical Laboratories, Medical Staff Office, Surgical Pathology and Pharmacy computer data bases, the Patient Care Evaluation computer analyzes information on hospital resource utilization. This includes both length of stay information and ancillary services utilization.

Inpatients are identified as being at high risk for increased length of stay. This may be because of their insurance status, personal disabilities, or presumed DRG. These patients are actively followed by our Utilization Review Department who continually update a computer data base on the status of patients with regard to their assumed length of stay, diagnoses, operative procedures and planned disposition.

Ancillary service utlization is also monitored through this system. One example of use of the computer is the cross-tabulation of the number of patients receiving oxygen therapy with those who have blood gases done. It is interesting that in fiscal year 1984, there were 14,166 patients treated with oxygen therapy. Of that number, 38.7% had an arterial blood gas. Obviously, from this information the appropriateness of this therapy cannot be determined. However, it may raise questions that would enable reviewers to focus on appropriate issues in order to aid in the reduction of ancillary services.

Another type of analysis that can be done is the profiling of patient length of stay by physician. The average actual length of stay can be compared with the targeted length of stay as indicated by DRGs by physician. From this information and other information regarding hospital costs, it is possible to determine the profit and loss for a particular physician given his admitting patterns and utilization of ancillary services. This information can then be helpful in identifying areas in which further investigation might take place.

Clearly, there may be certain circumstances which explain great disparities in targeted length of stay from actual length of stay. For instance, a specific physician may have many patients with unusual diagnoses or undergoing complex procedures, as might be the case for a physician in charge of the Burn or Dialysis Unit.

Patient Care Support System

The Patient Care Support System is a multi-million dollar hospital-wide computer system for admissions, discharges and transfers and clinical information. Clinical information includes the ordering of all tests and procedures, charging, and results reporting. This system is currently being developed.

Obviously, a clinical information system such as this provides limitless opportunities to clinicians. Information can be transmitted to the physician as he is ordering the test or procedure. For instance, the physician can view the correct diet needed for a 24 hour urine for VMA or the indication for a particular type of medication. In addition, the system can check for drug interactions and allergies when ordering medications. Test/test interactions can be identified to help the physician avoid ordering duplicate or unnecessary tests, or tests that would interfere with one another within a certain period of time. Eventually, other systems currently being developed throughout the country might be accessed such as a computer diagnosis system or searches of library information via Medline.

Policy Changes

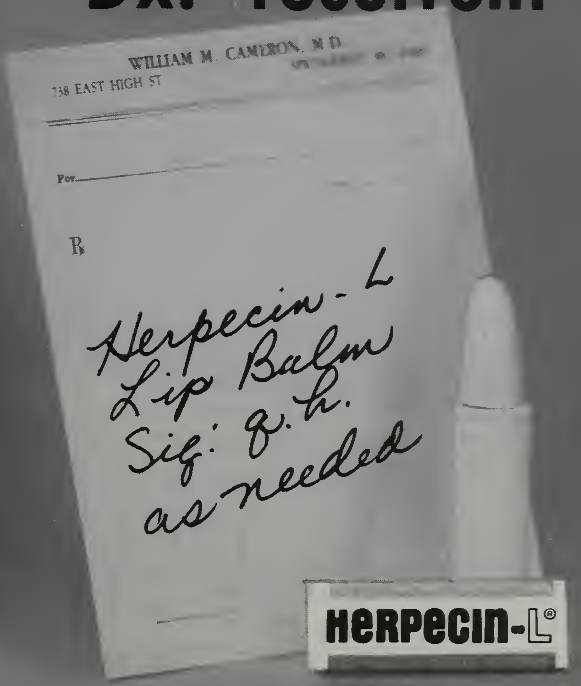
The computer revolution has brought tremendous new capabilities to practicing physicians, health care professionals and hospital managers. However, this revolution has also brought with it the need to change many of our plicies and concepts regarding patient care. The concept of the medical record as a written document stored in the basement of the hospital is rapidly changing. A medical record can now be electronically stored in an area less than the size of a dime. In fact, parts of the medical record may be duplicated in many computer systems, for instance, Pharmacy, Diagnostic Imaging, and Clinical Laboratories.

Obviously, this ability to transfer information rapidly to many different areas throughout a hospital requires taking a new look at patient and physician confidentiality. These items are being addressed at Yale-New Haven Hospital in the Medical Record and Clinical Information Committee. Clearly, the old safeguards of signing out a chart are no longer sufficient to ensure the right to privacy.

Another by-product of the computer revolution has been a new understanding of the Hospital and the interaction of patients and physicians. There are tremendous differences in perceptions versus reality once information is collected and collated. The computer provides us with a means of economically doing this. In developing the Patient Care Support System, we have gained a new understanding of who actually does the ordering on patients. Traditional concepts have held that the physician writes the orders in the medical record to be cosigned by the nurse and then transmitted to the ancillary service. However, this paradigm does not accurately represent the entire picture. Ordering actually takes place in a complex set of interactions among health care professionals and gets documented in a variety of ways including the patient's chart, requisitions, progress notes and reports.

The computer revolution has arrived. The challenge to physicians is to ensure that the information is correctly interpreted, used appropriately and with understanding. Clearly this must be done while remaining cognizant of issues of confidentiality and guidelines for the appropriate use of information.

Dx: recurrent herpes labialis



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Current Status of Therapeutic Plasmapheresis and Related Techniques:

Report of the AMA Panel on Therapeutic Plasmapheresis

AMA COUNCIL ON SCIENTIFIC AFFAIRS

ABSTRACT—The proper role of apheresis as a treatment modality is gradually becoming better defined. Controlled trials are now either completed or under way for most of the common entities for which apheresis has been applied. Data from these, as well as a number of uncontrolled studies, have been evaluated to assess the likelihood that apheresis will be helpful in a given clinical situation, and the conclusions are presented in this report.

After Abel et al coined the term "plasmapheresis" in 1914, widespread interest in this special form of bloodletting as a therapeutic modality had to await the development of practical equipment for performing safe and efficient plasma exchanges. The introduction of continuous- and intermittent-flow centrifuges in the 1960s, followed more recently by flat- and hollow-fiber filtration devices, simplified the procedure. Now plasmapheresis is a practical consideration in clinical situations in which pathogenic materials can be removed effectively from the body in plasma, and numerous reports of treatment of many diseases with plasmapheresis or related procedures have been published during the past decade. In diseases in which pathogenic mechanisms are known (or thought to be known), the rationale is to remove the pathogenic material from the circulation; examples include autoantibodies (eg, glomerular basement membrane antibodies in Goodpasture's syndrome), immune complexes (DNA: anti-DNA in systemic lupus erythematosus), and other toxic materials (phytanic acid in Refsum's disease). In other diseases, such as scleroderma, polymyositis, multiple sclerosis, the rationale is not so clear, but reports of the efficacy of plasmapheresis exist for all of these conditions.

The purpose of this report is to summarize the available data on the clinical utility of plasmapheresis as a therapeutic modality. A more comprehensive version is being published separately and is available from the American Medical Association. Periodically updated bibliographies also are available on request from the American Red Cross and the International Society for Artificial Organs.

Plasmapheresis Technology

Although it is possible to carry out plasmapheresis "manually" (or, more properly, "off-line") by drawing off blood a unit at a time, centrifuging it, discarding the plasma, recombining the cells with replacement fluid, and returning this mixture to the patient, this laborious procedure has been obviated by the development of continuous- and intermittent-flow centrigures, which permit safe and efficient "on-line" removal of plasma and/or certain cellular constituents of blood. Cytapheresis has been employed primarily for preparative purposes; using this technology, platelets and leukocytes can be collected from single donors in sufficient numbers to be clinically useful. However, erythrocytapheresis, leukocytapheresis, lymphocytapheresis, and thrombocytapheresis also have been used therapeutically. More recently, flat and hollow-fiber filtration devices have become available; these can be used for plasma exchange but not for cytapheresis.

The effectiveness of plasmapheresis in removing a pathogenic material from the body depends on the rate

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The Panel members are as follows: Asa Barnes, M.D., Long Beach, CA; John D. Clough, M.D., Panel Chairman, Cleveland, OH; Ray W. Gifford, Jr., M.D., CSA Liaison, Cleveland, OH; G.F. Giordano, M.D., Tucson, AZ; Max I. Hamburger, M.D., Stony Brook, NY; John V. Jones, M.D., Halifax, Nova Scotia; D.O. Kasprisin, M.D., Tulsa, OK; Edmund J. Lewis, M.D., Chicago, IL; William Masland, M.D., Tucson, AZ.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve.

at which the pathogenic material is replaced during and following treatment, as well as on the degree to which the pathogenic material is accessible through the circulation. The kinetics of this procedure have been reviewed. Because of kinetic considerations, many investigators have considered approximately 1.5 plasma volumes to be the ideal amount exchanged during a single treatment. In plasmapheresis for removal of an autoantibody, there is evidence in some cases that a precipitous drop in antibody concentration may increase the rate at which the antibody is synthesized (rebound phenomenon). On the positive side, there is also some evidence that removal of immune complexes may enhance the function of intrinsic clearance mechanisms for complexes, thus aiding the elimination process.

Untoward Effects of Plasmapheresis

Although plasmapheresis is widely held to be a relatively safe procedure, a large number of adverse reactions have been attributed to it. Fortunately, the more common effects are relatively mild and the more severe reactions are rare (Table 1). The most severe untoward effects appear to occur mainly with the use of fresh frozen plasma. Of the more than 50 deaths associated with plasmapheresis reported, most have been linked with the use of fresh frozen plasma as replacement fluid. Problems associated with removal of drugs can be avoided simply by administering the drugs after rather than before apheresis.

Table 1

UNTOWARD EFFECTS OF APHERESIS

- Group I. Common
  - Hematoma
  - Paresthesias secondary to citrate anticoagulation
  - Vasovagel reactions

- Group II. Rare
  - Local infection
  - Transfusion-related infection (eg, hepatitis, AIDS)
  - Peripheral nerve trauma
  - Air embolus
  - Hypovolemic reactions
  - Bleeding due to depletion of platelets or coagulation component
  - Extracorporeal hemolysis
  - Respiratory distress
  - Cardiac arrhythmias
  - Hypersensitivity reactions

Systemic Lupus Erythematosus

Uncontrolled studies in systemic lupus erythematosus can be divided into three groups: (1) those that employed plasmapheresis alone, (2) those in which plasmapheresis was applied concomitantly with corticosteroids, and (3) those in which plasmapheresis was applied concomitantly with corticosteroids and cytotoxic drugs. In most of the uncontrolled studies, results were favorable, particularly in patients treated with a combination of plasmapheresis, corticosteroids, and cyclophosphamide. In the group treated with plasmapheresis alone, improvement was brief and clinical and/or immunologic deterioration occurred within one month in 42% of the patients. This has been interpreted by some as a "rebound" phenomenon and has led to the recommendation that plasmapheresis therapy in systemic lupus erythematosus be contraindicated without concomitant immunosuppressive therapy to prevent this phenomenon.

A single randomized controlled trial of plasmapheresis in 20 patients with mild systemic lupus erythematosus concluded that plasmapheresis has little to offer in mild forms of systemic lupus erythematosus, but it appears to be somewhat more promising in severe disease characterized by renal, central nervous system, or vasculitic complications. A multicenter controlled trial of "conventional" (prednisone plus cyclophosphamide) therapy versus the same therapy with plasmapheresis in active diffuse proliferative glomerulonephritis due to systemic lupus erythematosus is now under way and should help to clarify the role of plasmapheresis in treating severe forms of the disease.

At present, based on favorable reports in uncontrolled trials and in the absence of suitable controlled trials, it seems reasonable to consider plasmapheresis as a potential adjunct to conventional therapy in severe lupus. Most experienced observers agree that concomitant immunosuppressive therapy (eg, cyclophosphamide) should be used in severe disease.

Goodpasture's Syndrome

Although both spontaneous remission and improvement in response to drug therapy have been reported in Goodpasture's syndrome, the mortality rate is high. The association of this disease with antibody against glomerular basement membrane provides the rationale for plasmapheresis in Goodpasture's syndrome, and this antibody can be effectively removed. Uncontrolled studies have been favorable, although death from hemorrhage or infection occurs relatively frequently. The procedure appears to be most effective when used before significant irreversible renal damage has developed. It is invariably used with corticosteroids and/or immunosuppressive agents.

Rapidly Progressive Glomerulonephritis Due to Various Causes

Rapidly progressive glomerulonephritis is a histopathologic entity that may be associated with glomerular deposits of specific antibody (as in Goodpasture's syndrome), immune complexes (as in systemic lupus erythematosus and acute poststreptococcal glomerulonephritis), or no well-defined immunologic mechanism (eg, Wegener's granulomatosis, idiopathic rapidly progressive glomerulonephritis). In a series of patients with rapidly progressive glomerulonephritis associated with various conditions (including Wegener's granulomatosis and polyarteritis nodosa) as well as idiopathic rapidly progressive glomerulonephritis, a British group has reported clinical improvement following plasmapheresis and has shown the superiority of plasmapheresis plus cyclophosphamide over combination therapy with corticosteroids, azathioprine, and cyclophosphamide. Inter-

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pretation of these data remains difficult because of lack of homogeneity in the patients studied. Nonetheless, plasmapheresis may be considered potentially effective in rapidly progressive glomerulonephritis as an adjunct to more conventional therapy.

Renal Allograft Rejection

Results of a number of anecdotal reports have suggested that plasmapheresis or lymphocytoplasmapheresis may be effective in controlling allograft rejection. In the single available controlled trial, no marginal benefit of plasmapheresis was demonstrated after three months. However, it should be noted that the control group in this study did extremely well, and the demonstration of statistically significant marginal benefit would have required near perfection in the plasmapheresis group or a very large number of patients in the study. Uncontrolled trials utilizing lymphocytoplasmapheresis have suggested that this procedure may be efficacious. Although confirmation is necessary, encouraging early reports seem to justify lymphocytoplasmapheresis and, perhaps, plasmapheresis as desperation therapy in allograft rejection.

Hyperviscosity Syndrome

One of the earliest applications of therapeutic plasma exchange was in the treatment of hyperviscosity syndrome, including those cases in which the syndrome was produced by paraproteinemias. This treatment is clearly effective, and because of slow reaccumulation of paraproteins, particularly in Waldenstrom's macroglobulinemia, therapy may not have to be performed frequently. A grave complication of myeloma due to the deposition of light chains in the kidney has also reportedly responded to plasmapheresis. Clearly, plasmapheresis is first-line therapy in symptomatic hyperviscosity syndrome and should be used along with treatment of the primary disease.

Hemophilia with Factor VIII Inhibitor

Plasmapheresis has been reported to be effective in controlling hemorrhage in both hemophiliacs and nonhemophiliacs with inhibitors to factor VIII-C. It also can be used to prepare hemophiliac patients with inhibitors for surgery. Some hemophiliac patients without inhibitors have been prepared for surgery using plasma exchange with fresh frozen plasma as replacement fluid, which allows adequate quantities of clotting factor to be supplied without the high risk of hepatitis that is present with the concentrates. Plasmapheresis with appropriate coagulation factors in the replacement fluid is thus indicated in hemophiliac patients with factor VIII inhibitors when the plasma inhibitor titer is too high to be overcome by using larger doses of factor VIII and when more conventional therapy with activated prothrombin complex concentrate has failed (a) if a significant hemorrhage requires blood component therapy or (b) if elective surgery is planned. Immunosuppression may be necessary in selected cases when prolonged therapy will be required.

Maternal Fetal Incompatibility

The idea of using plasmapheresis during pregnancy to reduce levels of maternal IgG antibodies directed against blood group antigens present in the fetus is attractive, but the results of trials of this form of therapy have been mixed. Although the fetal survival rate has been improved with plasmapheresis, in some studies a sudden rise in antibody levels occurred during plasma exchange. It has been suggested that this may be due to a leak of red cells from the fetus into the mother's circulation during pregnancy; alternatively, it may be due to removal of regulatory factors during plasmapheresis. In addition, sepsis associated with plasmapheresis in this situation has been reported and, if fresh frozen plasma is used as replacement, the risk of hepatitis must also be considered. If fresh frozen plasma is used, it must be from Rh-negative donors to avoid the risk of infusing any Rh-positive erythrocytes. Because of the preliminary nature of the data in this condition, plasmapheresis should be restricted to those cases of maternal fetal incompatibility in which there is a high risk of fetal demise and in which early delivery or intrauterine transfusion are not possible.

Autoimmune Cytopenias

Plasmapheresis has been tried in all of the autoimmune cytopenias, including the autoimmune hemolytic anemias, idiopathic thrombocytopenic purpura, post-transfusion purpura, and the cytopenias of system lupus erythematosus as well as in some cases of Felty's syndrome. All of these conditions are thought to be mediated by antibodies, and this provides the rationale for use of plasmapheresis. With the exception of post-transfusion purpura, however, the results of plasmapheresis in these disorders have been somewhat disappointing, and the combination of plasmapheresis with other forms of therapy has made interpretation of the results difficult. At present, more information needs to be obtained in order to determine the role of plasmapheresis, if any, in the treatment of these disorders.

Leukemia

Leukocytapheresis has been used successfully for rapid reduction of high white cell counts with sludging in patients with both acute and chronic leukemias. However, since leukocytapheresis has not been shown to be useful for maintenance therapy, it presently cannot be recommended for long-term control. A possible exception may be hairy cell leukemia, in which two investigators have described excellent long-term remission with leukocytapheresis.

Cancer

The rationale for considering plasmapheresis in the treatment of cancer relates to the possibility that tumor-specific immune response results in the generation of blocking factors (either specific antibody or immune complexes), the removal of which would be beneficial. Although interest in this area persists, definitive studies demonstrating efficacy remain to be performed, although some early results appeared encouraging.

Thrombocytosis

The use of thrombocytapheresis in patients with symptomatic thrombocytosis has been suggested in order to prevent the major complications of this condition, which include cerebral ischemia, myocardial ischemia, extremity ischemia, pulmonary infarction, and hemorrhage. Some causes of severe thrombocytosis can be treated with drugs, but patients remain vulnerable to the effects of thrombocytosis during the period (up to several weeks) after initiation of therapy and before reduction in platelet counts is achieved; in contrast, thrombocytapheresis reduces counts immediately. Current recommendations are that thrombocytapheresis be reserved for symptomatic patients or for those with platelet counts above 10 in whom surgery is planned. Reduction in counts to levels below $10^{6}mm^{3}$ is not considered necessary.

Thrombotic Thrombocytopenic Purpura

Thrombotic thrombocytopenic purpura is a severe disease characterized by thrombocytopenia, renal failure, and central nervous system manifestations. Corticosteroids and immunosuppressive drugs historically have produced little or no effect, but the empirical application of exchange transfusion and later plasma exchange using fresh frozen plasma as replacement fluid has yielded better results. At present, the treatment of choice for thrombotic thrombocytopenic purpura is exhaustive plasma exchange with fresh frozen plasma as replacement fluid. A Canadian study is now under way to determine whether the administration of fresh frozen plasma without exchange will be equally effective.

In hemolytic uremic syndrome, a similar condition, plasmapheresis therapy also has been tried with some initial encouraging results, but the number of cases treated so far is too small to yield any firm conclusions.

Congenital Metabolic Diseases

Certain congenital metabolic diseases, such as homozygous familial type IIA hyperlipoproteinemia and Refsum's disease, can be treated effectively with plasmapheresis in combination with an appropriate diet. In both conditions, biweekly or weekly treatments are necessary throughout life in order to maintain cholesterol or phytanic acid levels within a tolerable range. Results in Febry's disease have not been encouraging.

Myasthenia Gravis

With recognition of the apparent pathogenic role of antibodies against the acetylcholine receptor in myasthenia gravis, the rationale for use of immunomodulating therapies, including plasmapheresis, in this disorder was established. A number of reports of the efficacy of plasmapheresis in acute myasthenia have been published, but most investigators now reserve this procedure for patients with acute myasthenic crises; for those with chronic disease who cannot be managed adequately by anticholinesterase drugs, thymectomy, or immunosuppressive therapy; and for use preoperatively. The exact protocols to be followed in each case depend upon the therapeutic goal and effectiveness of the plasma exchange.

Multiple Sclerosis

Based on the assumption that multiple sclerosis is an autoimmune disease, both plasmapheresis and lymphocytapheresis have been tried as treatment modalities. Results have been mixed. Several uncontrolled trials reported benefits while others did not. A controlled trial in which plasmapheresis plus azathioprine was compared to azathioprine alone showed no difference between the two treatments. (It should be noted that the efficacy of azathioprine in multiple sclerosis has not been established.) In a more recent controlled study of 59 patients, a statistically significant improvement in disease activity was observed with plasmapheresis and immunosuppressive drugs compared to immunosuppressive drugs (cyclophosphamide and prednisone) alone. Lymphocytapheresis also has been tried in uncontrolled studies and appears promising; best results have been obtained in patients with moderately progressive disease.

Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is a disease of unknown etiology in which certain immunologic abnormalities may be demonstrated. Uncontrolled studies and one small controlled trial utilizing plasmapheresis have failed to show any improvement, and it appears unlikely that plasmapheresis will play a role in the treatment of this disease.

Inflammatory Polyradiculoneuropathies

Both acute and chronic polyradiculoneuropathies have been treated with plasmapheresis. In the acute form (Guillain-Barre syndrome when idiopathic), the value of plasmapheresis has been difficult to assess because spontaneous remissions are the rule. Overall results of a recent multicenter controlled trial have not yet been released, but in a preliminary evaluation at one center the results appear to be promising. In the chronic form, plasmapheresis appears to be worth attempting as a last resort when corticosteroid therapy fails. This conclusion is supported by two small controlled trials and a number of uncontrolled observations.

Rheumatoid Arthritis

Both plasmapheresis and lymphocytapheresis have been tried in rheumatoid arthritis. Results of a number of uncontrolled trials suggested that plasmapheresis might be effective in this disorder but these have not been confirmed in controlled trials; thus, the value of plasma exchange in the treatment of rheumatoid arthritis is now considered doubtful. However, two controlled trials have demonstrated statistically significant, though modest, improvement when lymphocyte depletion is combined with plasmapheresis or is carried out by itself. Current principles that should guide the use of this treatment include: (a) failure to respond to at least two slow-acting agents; (b) active but reversible (not stage IV) disease; (c) co-administration of a slow-acting agent; and (d) no contraindications (eg, significant cardiovascular or cerebrovascular disease). In studies demonstrating efficacy, 5×10^9 to 5×10^{11} lymphocytes were removed. Neither the optimal degree of lymphocyte depletion necessary to achieve the clinical goals nor the long-term hazards of this type of treatment are known.

Rheumatoid Vasculitis

Standard plasma exchange has yielded promising results in a number of patients treated for this life-threatening complication of rheumatoid arthritis. Immune complexes are lowered and ischemic lesions are improved. Neuropathy is more refractory to such therapy. No controlled trials are available.

Other Forms of Vasculitis

Leukocytoclastic angiitis (including rheumatoid vasculitis) is the histopathologic form of vasulitis most clearly associated with circulating immune complexes. Included in this group of disorders are hypersensitivity vasculitis, Henoch-Schonlein purpura, mixed cryogloobulinemia with vasculitis, vasculitis with connective tissue diseases, vasculitis associated with malignancies, urticarial (hypocomplementemic) vasculitis, and vasculitis associated with certain other primary disorders. Although controlled trials are not available, improvement has been reported in polyarteritis nodosa, cryoglobulinemia with vasculitis, Henoch-Schonelin purpura, leukocytoclastic vasculitis of unknown etiology, and rheumatoid vasculitis. For these conditions, in which conventional treatment produces poor or unpredictable results, the use of plasmapheresis seems justified in life-threatening situations based on favorable response in uncontrolled studies.

Miscellaneous Rheumatic Conditions

Favorable results have been reported in an uncontrolled trial of plasmapheresis in progressive systemic sclerosis. This study awaits confirmation.

In uncontrolled trials improvement following plasmapheresis in both adult and childhood forms of polymyositis dermatomyositis has been observed. Patients had been refractory to prednisone and immunosuppressive therapy prior to institution of plasmapheresis. These encouraging results need to be confirmed in controlled studies.

Plasmapheresis has been tried in limited numbers of patients with juvenile rheumatoid arthritis and psoriatric arthritis with mixed, although somewhat promising, results. Considerably more information is needed to establish the efficacy of plasmapheresis in these and other inflammatory arthritic conditions in which a clear rationale for plasmapheresis does not exist.

Liver Disease

Exchange transfusion and, later, plasmapheresis offered some hope of improving survival in fulminant hepatic failure following hepatitis in small, uncontrolled series. However, both procedures were subsequently studied in controlled trials and results were disap-pointing. Interest now focuses on plasmaperfusion therapy using absorbents to remove toxic materials from the circulation in various forms of liver disease, including chronic hepatic failure following hepatitis, encephalopathy associated with portal cirrhosis, primary biliary cirrhosis, and pruritus associated with cholestatic jaundice.

Thyroid Disease

Reports of the use of plasmapheresis for removal of thyroid hormones in thyrotoxic crisis (occurring naturally or through ingestion of excess thyroid hormone) have been encouraging, although treatment must be exhaustive to be effective. However, a controlled study has demonstrated no benefit in Graves' ophthalmopathy.

Skin Disorders

Removal of antibody against intercellular cement substance provides the rationale for using plasmapheresis in the treatment of pemphigus, and preliminary reports suggest this procedure may be useful in combination with corticosteroids. In psoriasis, however, results of a small controlled study demonstrated that plasmapheresis was not beneficial.

Summary: Indications for Apheresis

The efficacy of plasmapheresis remains unproved in a number of conditions that might be expected to respond on theoretical grounds. In some of these situations, however, it is not unreasonable to consider the use of this treatment when conventional, first-line therapy has failed. One of the leading reasons is the relative safety of plasmapheresis compared to other therapy of comparble potency. Balanced against this are the high cost of plasmapheresis and the fact that multiple procedures are considered necessary in most conditions. Moreover, immunosuppressive therapy often is recommended as an adjunct to plasmapheresis negating some of the attractiveness of plasmapheresis from the standpoint of safety.

Those diseases for which there is available information are divided into four groups according to the likelihood that plasmapheresis or one of its variants may be effective. (Table 2) In the first category, are those few diseases for which plasmapheresis is considered to be first-line therapy—acceptable but not mandatory; none of these conditions is common, and most are rare. In the second category are diseases in which apheresis may be helpful but is not considered essential, initial therapy. Depending on the situation, apheresis need not be withheld until the situation is desperate, but some form of more conventional therapy usually would be instituted and given a reasonable trial first. In most of these conditions, there is at least some information in the literature supporting efficacy, althoug documentation tends to be less rigorous. In the third

Table 2

INDICATIONS FOR APHERESIS

Category I. Standard therapy, acceptable but not mandatory
- Hyperviscosity
- Myasthenia gravis
- Idiopathic rapidly progressive glomerulonephritis (RPGN)
- Goodpasture's syndrome (without anuria or with pulmonary hemorrhage)
- Rapidly progressive glomerulonephritis secondary to vasculitis
- Refsum's disease
- Thrombotic thrombocytopenic purpura
- Thyroid storm or thyroid hormone overdose
- Overdose with certain drugs
- Severe acute polyradiculoneuropathy (Giullain-Barre syndrome)
- Leukemia (for acute debulking only)*
- Thrombocytosis (symptomatic or presurgical)**
- Sickle cell syndrome***

Category II. Available evidence tends to favor efficacy; conventional therapy usually tried first
- Systemic lupus erythematosus
- Vasculitis without renal disease
- Cryoglobulinemia
- Familial hyperlipoproteinemia, type IIA, homozygous form
- Renal transplant rejection
- Post-transfusion purpura
- Renal failure with myeloma
- Hemophilia with factor VIIIc inhibitors
- Maternal fetal incompatibility
- Cholestasis with intractable pruritus
- Hairy-cell leukemia (maintenance)*
- Rheumatoid arthritis****
- Multiple sclerosis****

Category III. Inadequately tested this time
- Progressive systemic sclerosis
- Raynaud's phenomenon
- Polymyositis/dermatomyositis
- Psoriatic arthritis
- Juvenile rheumatoid arthritis
- Chronic polyradiculoneuropathy
- Goodpasture's syndrome (with anuria, without pulmonary hemorrhage)
- Idiopathic thrombocytopenic purpura
- Pemphigus
- Chronic hepatic failure
- Fabry's disease
- Multiple sclerosis
- Autoimmune hemolytic anemia
- Aplastic anemia
- Cancer
- AIDS
- Burn-shock
- Miscellaneous hyperlipidemias
- Asymptomatic thrombocytosis**

Category IV. No demonstrated value in controlled trials
- Psoriasis
- Amyotrophic lateral sclerosis
- Rheumatoid arthritis

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*	Leukocytapheresis (for debulking)
**	Thrombocytapheresis
***	Erythrocytapheresis
****	Lymphocytapheresis ± plasmapheresis

All others are standard plasmapheresis

category are diseases in which plasmapheresis should be used only in the investigative setting or as a last resort under extraordinary clinical circumstances after conventional treatment has failed. Controlled clinical studies are needed in the second and third groups of diseases to ultimately determine the effectiveness of apheresis. In the fourth category are diseases for which controlled studies of apheresis appear to have failed to show reasonable evidence of efficacy. At this point, apheresis is not recommended for diseases in this category, even as a desperation measure.

One important area of progress in apheresis is the further development of technology, permitting ever greater selectivity in the material targeted for removal. Theoretically, this should permit safer use of exhaustive protocols, since only the putative pathogenic molecules would be removed. Moreover, significant savings in the cost of replacement fluids, one of the limiting factors in large-scale use of standard plasmapheresis, should result. Obviously, before therapy of this type can become practical, considerably more must be learned about the details of pathogenesis of the diseases to be treated, a major challenge facing practitioners of apheresis in the years to come.

Closed Medical Staffs Are Not Inevitable

JACK A. SKARUPA AND THOMAS R. MATHERLEE

Despite symptoms in the new health care environment that could lead to the conclusion that closed medical staffs are inevitable, no great rush is under way among hospital governing boards to close medical staffs. Further, the industry is becoming so diverse that it is extremely difficult to determine how any hospital will react to a set of circumstances, including the circumstances that shape the composition of the medical staff.

In terms of one symptom, the physician supply, 1983 statistics indicate almost 520,000 physicians overall, and 423,000 whose primary activity is patient care. That's an increase of 3.6 percent over 1982. A more telling statistic is that, by 1990, almost half of all physicians will have graduated since 1975. That means young physicians will be seeking admission to medical staffs, competing with each other and with older, more established physicians. But rather than the closing of medical staffs based purely on physician supply, I see the marketplace shifting physicians to more underserved, rural communities and into the specialties that are in greater demand.

In addition to the increased physician supply, an element of competition was injected in the marketplace when the JCAH opened hospital privileges to limited-licensed practitioners. But we are not seeing a great rush of applications by these people for positions on the medical staff. Although limited-license practitioners may be granted clinical privileges without having full medical staff membership, admitting privileges remain available only to members of the medical staff.

Another perceived symptom is the increased number of health maintenance organizations. We may see closed staffs when a hospital and its physicians sell their services as a package in the form of an HMO. Still, this is not always the case, especially when the hospital is the only facility in the community.

Still another symptom is the impact of prospective pricing on the hospital and its medical staff. But although hospital occupancy rates are down, I believe hospitals will keep medical staffs open, especially to physicians who can demonstrate their efficiency in relation to limited resources.

Yet the same environment that has produced these symptoms has generated great diversity among hospitals. Whereas hospitals once were a homogeneous lot, there are now a greater number of specialized interests among hospitals—urban and rural, for-profit and not-for-profit, multihospital systems, teaching facilities, and those with concentrations in areas such as rehabilitation and long-term care.

Because of this diversity, a broad range exists in the degree to which medical staffs become closed. At one end are teaching institutions that may always have had a closed medical staff because of the necessary commitment by faculty members to that institution. The medical staffs of a great number of community hospitals, either for-profit or not-for-profit, range from open to closed and all points in between, including closure of a clinical department or a certain subspecialty, while the rest of the medical staff remains open.

If there is a factor that changes the traditional basis upon which the nature of the medical staff is selected, that factor would be the revised JCAH medical staff standards. Their effect will be to eliminate national standards for the privileging process and to focus on the institution-specific variables that should determine the composition of the medical staff. One section of revised Standard IV (B) states, "The mechanism by which the applicant requests, the executive committee of the medical staff recommends, and the governing body grants clinical privileges is hospital-specific." So, with the increasing diversity of the hospital industry, there will be increasing diversity in the

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JACK A. SKARUPA, President of Greenville Hospital System, Greenville, SC; Chairman of the American Hospital Association's Board of Trustees for 1985. He is a fellow of the American College of Hospital Administrators, and a member and past president of the South Carolina Hospital Association. THOMAS R. MATHERLEE, President of Gaston Memorial Hospital, Gastonia, NC; Speaker of the House of Delegates of the American Hospital Association for 1985. He is a Fellow of the American College of Hospital Administrators and past president of the North Carolina Hospital Association.

criteria by which members of the medical staff are selected.

JCAH Standard I states that minimum professional criteria include evidence of current licensure, relevant training and/or experience, current competence, and health status. The standard goes on to specifically recognize the validity of such additional criteria as the ability of the hospital to provide adequate facilities and support services, patient care needs for additional staff members, evidence of liability insurance, and geographic location of the applicant.

Recent survey data from the American Hospital Association suggest that concerns over a trend toward closed staffs may have been fueled by confusion over just what constitutes a closed medical staff and by the prevalence of exclusive contracts with physicians. In the survey, the AHA defined medical staff as "closed" if one or more clinical department services or specialties did not accept new applications for any category of medical staff membership or clinical privileges, either temporarily or for an indefinite period of time. A closed staff situtation also exists, according to the AHA, if there is a "moratoriam" on making new medical staff appointments and granting clinical privileges. Exclusive contracts were explicitily excluded from this definition.

The results of the survey, using this definition of a closed medical staff, suggest that an overwhelming majority of hospitals actually are *not* moving to close their medical staffs. Indeed, as of January 1, 1984, only 3.4 percent of hospitals had medical staff bylaws provisions for the closing of all or part of the medical staff. While almost all hospitals reported that they were in the process of revising their medical staff bylaws, only 9.5 percent indicated that they were dealing with closed medical staff issues. Further, in calendar 1983 the typical hospital received 24.6 applications for medical staff membership and accepted 92 percent of the applications. Only 2.6 percent of hospitals received no applications, and of those receiving applications, 99 percent accepted at least one.*

Therefore, it seems clear that hospital action in the future will not be to close the medical staff, but to evaluate staffing according to these very diverse, institution-specific variables and to be more selective in choosing medical staff members who are well aware of the institution's basic need for efficient use of its resources. Leaving the staff open, but being more selective, will allow the hospital greater flexibility to meet changing health care needs in our new environment.

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*Morrisey MA and Brooks DC. The myth of the closed medical staff. Hospitals, JAHA, July 1, 1985.

IN MEMORIAM

CHERRY, JOSEPH B., McGill University, 1943. Dr. Cherry was a general surgeon in the Fairfield County area since 1951. From 1952 to 1956, he was clinical instructor in surgery at Yale University. Dr. Cherry was senior attending surgeon at Danbury Hospital, where he was chief of surgery from 1962 to 1968 and chairman of the medical staff from 1969 to 1972. Also, he was vice president, treasurer and director of Glen Hill Convalescent Center, Danbury, since 1961. Dr. Cherry was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 21, 1985 at the age of 63.

MOORE, MAURICE R., Queens College, 1929. Dr. Moore was an internist in the New London County area since 1936. He was a pathologist at Lawrence Memorial Hospital and Norwich State Hospital and retired emeritus from Backus Hospital. Dr. Moore was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 23, 1985 at the age of 84.

RIBNER, HAROLD, Tufts, 1934. Dr. Ribner was neurologist and psychiatrist in the Fairfield County area since 1936. He was formerly the chief of neuropsychiatry at Bridgeport Hospital for 20 years. Dr. Ribner was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 6, 1985 at the age of 77.

SEKERAK, RICHARD J., University of Maryland, 1934. Dr. Sekerak was an otolaryngologist in the Fairfield County area since 1934. He was a former president of the staff of St. Vincent's Medical Center of Bridgeport, and an assistant clinical professor at the Yale University School of Medicine. Dr. Sekerak was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 30, 1985 at the age of 76.

SLATER, MORRIS, Yale, 1924. Dr. Slater was general practitioner in the New Haven County area since 1924 and later went into the practice of dermatology. He was on the courtesy staff of Yale-New Haven Hospital and Griffin Hospital. Dr. Slater was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association, died July 2, 1985 at the age of 88.

TWACHTMAN, ERIC, University of Virginia, 1936. Dr. Twachtman was a general practitioner in the Middlesex County area since 1939. He was on the courtesy staff of the Middlesex Memorial Hospital. Dr. Twachtman was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 16, 1985 at the age of 75.

Revision of Case Definition of Acquired Immunodeficiency Syndrome for National Reporting—United States

CENTERS FOR DISEASE CONTROL

Patients with illnesses that, in retrospect, were manifestations of acquired immunodeficiency syndrome (AIDS) were first described in the summer of 1981.[1,2] A case definition of AIDS for national reporting was first published in the *MMWR* in September 1982.[3,4] Since then, the definition has undergone minor revisions in the list of diseases used as indicators of underlying cellular immunodeficiency.[5-8]

Since the 1982 definition was published, human T-cell lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) has been recognized as the cause of AIDS. The clinical manifestations of HTLV-III/LAV infection may be directly attributable to infection with this virus or the result of secondary conditions occurring as a consequence of immune dysfunction caused by the underlying infection with HTLV-III/LAV. The range of manifestations may include nothing, nonspecific signs and symptoms of illness, autoimmune and neurologic disorders, a variety of opportunistic infections, and several types of malignancy. Acquired Immunodeficiency Syndrome was defined for national reporting before its etiology was known and has encompassed only certain secondary conditions that reliably reflected the presence of a severe immune dysfunction. Current laboratory tests to detect HTLV-III/LAV antibody make it possible to include additional serious conditions in the syndrome, as well as to further improve the specificity of the definition used for reporting cases.

The current case definition of AIDS has provided useful data on disease trends, because it is precise, consistently interpreted, and highly specific. Other manifestations of HTLV-III/LAV infections than those currently proposed to be reported are less specific and less likely to be consistently reported nationally. Milder disease associated with HTLV-III/LAV infections and asymptomatic infections may be reportable in some states and cities but will not be nationally reportable. Because persons with less specific or milder manifestations of HTLV-III/LAV infection may be important in transmitting the virus, estimates of the number of such persons are of value. These estimates can be obtained through epidemiologic studies or special surveys in specific populations.

Issues related to the case definition of AIDS were discussed by the Conference of State and Territorial Epidemiologists (CSTE) at its annual meeting in Madison, Wis., June 2 through 5, 1985. The CSTE approved the following resolutions:

1. that the case definition of AIDS used for national reporting continue to include only the more severe manifestations of HTLV-III/LAV infection;
2. that the CDC develop more inclusive definitions and classifications of HTLV-III/LAV infection for diagnosis, treatment, and prevention, as well as for epidemiologic studies and special surveys;
3. that the following refinements be adopted in the case definition of AIDS used for national reporting:
   a. In the absence of the opportunistic diseases required by the current case definition, any of the following diseases will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-III/LAV:
      (1) disseminated histoplasmosis (not confined to lungs or lymph nodes), diagnosed by culture, histology, or antigen detection;
      (2) isosporiasis, causing chronic diarrhea (more than one month), diagnosed by histology or stool microscopy;
      (3) bronchial or pulmonary candidiasis, diagnosed by microscopy or by presence of characteristic white plaques grossly on the bronchial mucosa (not by culture alone);
      (4) non-Hodgkin's lymphoma of high-grade pathologic type (diffuse, undifferentiated) and of B-cell or unknown immunologic phenotype, diagnosed by biopsy;
      (5) histologically confirmed Kaposi's sarcoma in patients who are 60 years old or older when diagnosed.
   b. In the absence of the opportunistic diseases required by the current case definition, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis in a child (younger than 13 years of age) will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative.
   c. Patients who have a lymphoreticular malignancy diagnosed more than three months after the diagnosis of an opportunistic disease used as a marker for AIDS will no longer be excluded as AIDS cases.
   d. To increase the specificity of the case definition, patients will be excluded as AIDS cases if they have a negative result on testing for serum anti-body to HTLV-III/LAV, have no other type of HTLV-III/LAV test with a positive result, and do not have a low number of T-helper lymphocytes or a low ratio of T-helper to T-suppressor lymphocytes. In the absence of test results, patients satisfying all other criteria in the definition will continue to be included.

The CDC will immediately adopt the above amendments to the case definition of AIDS for national reporting. This revision in the case definition will result in the reclassification of less than 1% of cases previously reported to the CDC. The number of additional new cases reportable as a result of the revision is expected to be small. Cases included under the revised definition will be distinguishable from cases included under the old definition so as to provide a consistent basis for interpretation of trends. The CDC will also develop draft classifications for disease manifestations of HTLV-III/LAV infections other than AIDS, distribute these widely for comment, and publish the results.

Reported by Conference of State and Territorial Epidemiologists; AIDS Br, Div of Viral Diseases, Center for Infectious Diseases, CDC.

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World Health Organization Workshop: Conclusions and Recommendations on Acquired Immunodeficiency Syndrome

An international conference on acquired immunodeficiency syndrome (AIDS), sponsored by the US Department of Health and Human Services and the World Health Organization (WHO), was held in Atlanta April 15 to 17, 1985. It was attended by more than 3,000 participants from 50 countries and was followed on April 18 through 19 by a WHO consultation to review the information presented at the conference and to assess its international implications.

The group of WHO consultants concluded that information is now sufficient to permit health authorities to take actions that may decrease the incidence of AIDS among certain risk groups. The group submitted the following conclusions and recommendations:

1. WHO should:

   a. Establish a network of collaborating centers with special expertise in the field. The centers should assist in training staff members and providing reference panels of serum samples, evaluation of diagnostic tests, and provision of advice on the production of working reagents. They should also assist in preparing educational material and organizing studies to determine the natural history of the disease and the extent of infection in different parts of the world.

   b. Coordinate global surveillance of AIDS using a compatible reporting format and the currently accepted case definition. WHO should disseminate these data and other important developments on the disease as widely and as rapidly as possible.

   c. Assist in developing an effective vaccine, and when appropriate, developing international requireents for the vaccines. WHO should take an active role in facilitating the evaluation of candidate vaccines.

   d. Encourage and assist in periodic serologic studies in countries where AIDS has yet to be recognized and should ensure the collection of comparable data and representative selections of serum samples, since lymphadenopathy-associated virus/human T-lymphotropic virus type III (LAV/HTLV-III) infection precedes AIDS in a person or a community, early recognition will require serologic studies in groups with potential risk of infections.

2. Member countries should:

   a. Inform the public that LAV/HTLV-III infection is acquired through heterosexual and homosexual intercourse, needle-sharing by intravenous drug abusers, transfusion of contaminated blood and blood products, transmission by infected mothers to their babies, and probably repeated use of needles and other unsterile instruments used for piercing skin/mucous membranes. Information should be provided about the risk of LAV/HTLV-III infection and AIDS, especially to those men and women who may be at increased risk because of multiple sexual partners. There is currently no evidence of spread of LAV/HTLV-III by casual social contact even within households. Provision of timely and accurate information on these points is recommended to allay inappropriate public concern.

   b. Ensure that medical workers are informed about AIDS and LAV/HTLV-III infection, modes of transmission, clinical spectrum, available programs of management (including psychosocial support), and methods for prevention and control.

   c. Assess the risk that AIDS poses to each country's population and establish methods of diagnosis, surveillance, and laboratory testing, including specific tests for LAV/HTLV-III.

d. Screen, where feasible, potential donors of blood and plasma for antibody to LAV/HTLV-III, and not use positive units for transfusion or for the manufacture of products where there is a risk of transmitting infectious agents. Potential donors should be informed about the testing in advance of the donation.

e. Reduce the risk of transmission of LAV/HTLV-III by factor VIII and IX concentrates by treating them by heat or other proven methods of inactivation. The use of such products is recommended.

f. Inform potential donors of organs, sperm, or other human material about AIDS, and encourage groups at increased risk of infection to exclude themselves from donating. Whenever possible, serologic testing should be performed before these materials are used. This is particularly important when donor material is collected from an unconscious or deceased patient on whom relevant information may be absent.

g. Refer persons with positive tests for antibody to LAV/HTLV-III for medical evaluation and counseling. Such people should be encouraged to inform their medical attendants of their status.

h. Develop guidelines for the total care of patients and for handling their specimens in hospital and other settings. These guidelines should be similar to those that have been effective for care of patients with hepatitis B.

i. Develop codes of good laboratory practice to protect staff against risk of infection. Such recommendations may be based on those found in the Laboratory Biosafety Manual published by WHO.[1] The level of care required for work with specimens from patients infected with LAV/HTLV-III is similar to that required with hepatitis B. The use of class II biologic safety cabinets is recommended. These cabinets are adequate for containment of other agents, such as herpes and hepatitis viruses, mycobacteria, and protozoa, that may be present in the specimens. For work involving production and purification of LAV/HTLV-III, P3 biosafety containment levels must be employed.

j. Collect and store serum samples from representative laboratory workers at the time of employment and at regular intervals thereafter, to be able to assess the risk of laboratory acquired infection and effectiveness of biosafety guidelines. Countries should provide this information to WHO for collation and dissemination. Provision of samples and testing should be carried out with the informed consent of the subjects.

k. Be aware of the importance of keeping confidential information about the results of serologic testing and the identity of patients with AIDS. Serologic testing should be undertaken with the informed consent of the subject.

Abstracted from WHO *Weekly Epidemiological Record* 60:129-139, 1985.

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Update: Lyme Disease and Cases Occurring During Pregnancy

Lyme disease is a tick-borne illness caused by a spirochete, *Borrelia burgdorferi.* The number of cases reported to the CDC has increased during the past two years so that Lyme disease is now the most commonly reported tick-borne illness in the United States. Although it is reportable in only a few states, informal national surveillance was initiated by the CDC in 1980 and has been compiled annually since 1982. In 1980, 1982, and 1983, 226,491 and 599 cases, respectively, were reported in the United States. In 1984, a provisional total of 1,498 cases was reported. For Lyme disease patients for whom 1983 and 1984 surveillance data are available, ages ranged from 1 year to 81 years (median, 34 years). Forty-four percent of cases occurred among men. Eighty percent of cases occurred during the four-month period from May to August, with the peak incidence in July.

Since 1980, reported cases of Lyme disease have occurred in an increasing number of states. Lyme disease was acquired in 11 states in 1980 and 1982, 18 states in 1983, and 21 states in 1984. Increasing numbers of cases have occurred in three states outside previously recognized endemic areas: Arkansas, North Carolina, and Texas. Isolated, serologically confirmed cases have been acquired in Florida, Georgia, Indiana, Michigan, New Hampshire, Virginia, and Tennessee. However, in all reporting years, more than 90% of all cases were acquired in only seven states: Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island, and Wisconsin. In addition to the states noted, isolated, clinically suspected but unconfirmed cases of Lyme disease have been reported from Kentucky, Maine, Missouri, Montana, Ohio, and Vermont.

The possible association between Lyme disease during pregnancy and adverse outcome has recently received attention. Transplacental transmission of *B burgdorferi* has been documented in a pregnant woman with Lyme disease who did not receive antimicrobial therapy. She delivered an infant with a congenital heart defect.[1] The relationship between the intrauterine infection and congenital heart defect has not been established. In an effort to assess the risk of Lyme disease during pregnancy, the state and territorial epidemiologists and the CDC have established a registry to enroll cases of Lyme disease in pregnant women before the outcome of pregnancy is known. Of the 19 pregnancies evaluated to date, none resulted in a child with a congenital heart defect. However, other adverse outcomes were found, including intrauterine fetal demise in the second trimester, prematurity, and developmental delay with cortical blindness. None of the adverse outcomes have been documented to be caused by Lyme disease. Outcomes of 14 of the pregnancies were completely normal. The risk of adverse outcome for pregnancies complicated by Lyme disease is not currently known.

Reported by State and Territorial Epidemiologists; Respiratory and Special Pathogens Epidemiology Br, Div of Bacterial Diseases, Center for Infectious Diseases, CDC.

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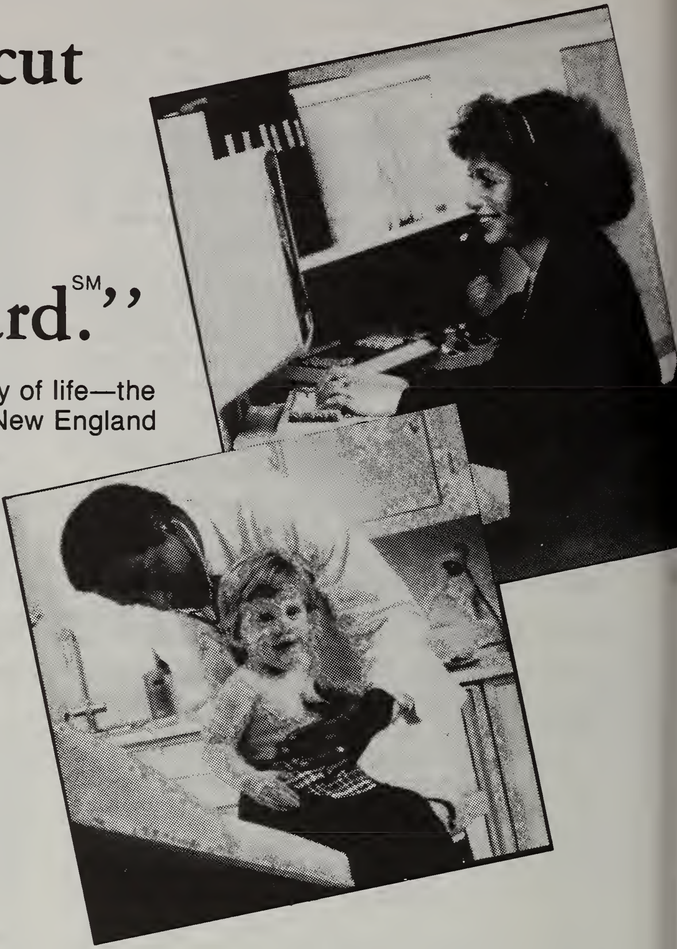

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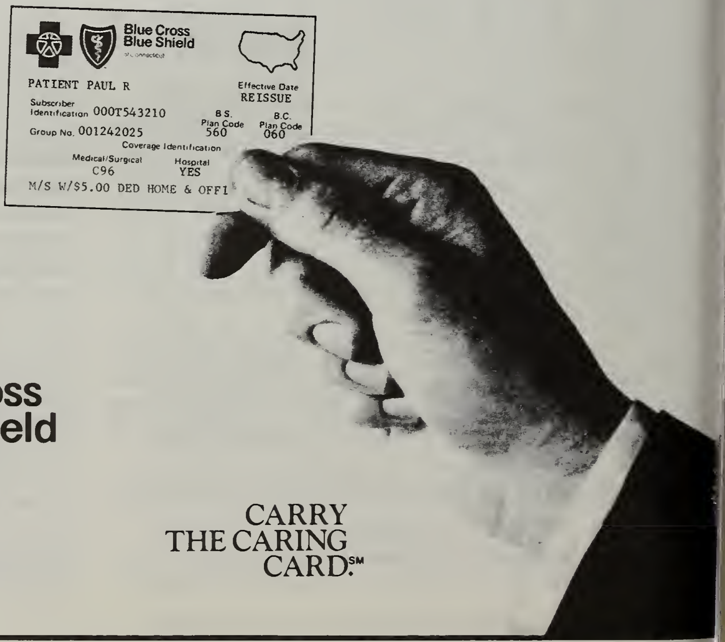

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The President's Page

No Compromise

The Connecticut General Assembly passed "An Act Establishing a Prospective Payment System for Hospitals", PA 84-315 which became effective June 5, 1985.

Section 4 of the Act provided that the Commission on Hospitals & Health Care (CHHC) require hospitals to submit such data as it deemed necessary for the development and implementation of the prospective payment system. Individual patient and physician data identified by proper name or personal identification code submitted pursuant to this section was to be kept confidential, but aggregate reports from which individual and physician data could not be identified was to be available to the public.

Neither the PA 84-315 nor any other statute presently authorizes the CHHC to collect any patient or physician data which are not "necessary" or "relevant" to the development and implementation of the prospective payment system. Despite the clear statements of authority and purpose embodied in PA 84-315, on May 14, 1985, the CHHC issued regulations which clearly demanded data in excess of what that required to "implement" and "administer" and "ensure compliance with" a prospective payment system. The regulations require that hospitals submit "the patient identification number, race, zip code, zip code suffix, name of attending physician, name of operating physician, admission status of any hospital patient, case outcomes, initials, birthdate, and hospital assigned code number of any physicians holding hospital staff privileges."

Confidential information is defined as information which "explicitly and implicitly identifies an individual patient or physician." The regulations issued by the CHHC threaten the privacy and confidentiality of patients and physicians. In the absence of proper confidentiality, it would be possible for anyone to learn the diagnosis, medical therapy, and therapeutic outcome on any individual patient treated in a hospital in the State of Connecticut. Such information would be available to members of the CHHC and its agents; it would be available to attorneys, employers, contractors, and the general public. The inherent danger is the misinterpretation and misuse of the information. Consider the violation of constitutional privacy and confidentiality rights of patients with psychiatric problems or those afflicted with AIDS or drug and alcohol addiction.

Certainly, the CHHC does not intend to violate the confidentiality rights of the citizens of Connecticut. To be sure, the CHHC is not trained nor is it legally authorized to perform the function of a peer review organization. The only other possibility is that the CHHC is attempting to establish a central registry of physician codes so that it may use the data to manipulate and control physician practice patterns under the guise of attempting to moderate health costs.

On June 14, 1985, a Petition for Declaratory Ruling was filed on behalf of the CSMS, CHA, three practicing physicians, and five general hospitals as a first step to challenge the actions of the CHHC. As a result of this action, a hearing has been scheduled and will have been held by the time this article is published. Subsequent strategy and action will develop following the hearing on August 19, 1985.

The Connecticut State Medical Society is on record having previously testified in firm opposition to the formation of a statewide central registry for physicians' codes. The present action of the CHHC is illegal and invalid. Confidentiality must be preserved! There is no compromise!!

William A. Whalen, M.D.
President

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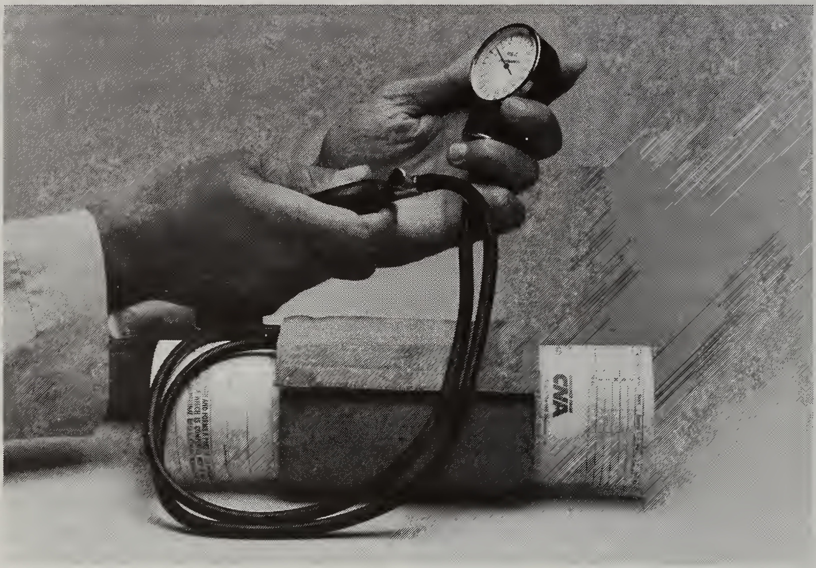

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Reflections on Medicine

First the Vision

ROBERT U. MASSEY, M.D.

Public education in America, in spite of its serious problems and insufficient support, has been a notable success; before the coming of radio and television the schools had more to do with making a nation of this vast republic than any other institution in our society. In schoolrooms from the Atlantic to the frontier, reading, writing, arithmetic, and the fundamentals of our public philosophy were transmitted to generations of native born and immigrant children.

The lifetime of one of the earliest educational reformers, Johann Heinrich Pestalozzi, (1746-1827) corresponds closely with that of one of the pioneers in public health, Johann Peter Frank (1745-1821). Both grew up in the borderlands between the Latin and German traditions; each represented the liberal faith of the Enlightenment that health and education were necessary to progress, happiness, and national wealth.

To understand how the public philosophy works to shape public policy we might examine the history of the public school movement, first in Europe, and then in this country. If there are analogies between public education and a system of public health, including essential medical care, this might help us clarify our thinking about health policy.

Although the history of public education was filled with petty sectarianism as well as noble idealism, there was a common vision of a free, happy, hard-working people which would lose the bonds of ignorance by providing for universal learning. All of this came long before the rise of scientific medicine and the reform of medical education; if there was an analogy, it was only with the ideas of public health and hygiene and the later matter of the social and economic place of medical care. Though differently stated, the issues rested mostly upon the same assumptions. Running throughout was the belief, not always explicit, that both public education and health were positive rights, serving the interests of the people and the state. The tension between paternalism and social welfare, and the conflict with freedom, was simply left there, unresolved in any final sense.

Also common to both has been the conviction that both public health and public education should be outside the market-place and above politics. Neither has ever been quite the case, but care has generally been taken to assure that both schools and medical institutions remain free from politics and profiteering. What has been lacking in the public philosophy of medical care, or public health, has been the powerful common vision which inspired the public school movement. Without such a vision we may despair of achieving agreement on policy.

"From 1890 to 1920 no other lay group had as much an impact on public education as did businessmen. Businessmen were active—to refashion urban systems on the corporate model;—they lavishly supported educational research—"[1] For different reasons, but generally for reasons of good business, corporate leaders have begun to take an interest in medical care and medical costs, and intend to make a difference. In education, the government boards, the teachers, the school administrators, the normal schools, and the businessmen worked together to fashion the public schools of the Progressive Era.

Something like that could happen in medicine, but there must first be a vision, an idealized concept of what medical care should be, as well as agreement on what it should not be. There is a public philosophy, expressed more or less explicitly in the past quarter century: just as no one may be denied public education, so no one may be denied essential medical services for lack of money to pay for it. That in itself would appear to take public education and essential health services out of the market-place.

We have spoken of 'rights' to medical care; perhaps 'obligation' would have been a better word. We have talked of health care and found that an elusive term. We have spoken of the health care 'industry' and within two years have seen medicine showing unmistakable signs of turning into a profit-making business. "Where there is no vision, the people perish."

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Connecticut's Living Will Statute

JOSEPH M. HEALEY, J.D.

Benjamin Cardozo, eminent American jurist, described in a 1914 legal opinion the root premise in American jurisprudence, that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . ."[1]. This principle of self-determination has been applied in the health care process through the development of the right to consent and the right to refuse treatment. In cases such as that involving Karen Ann Quinlan, discussed in last month's column, it has been established that these rights of self-determination are not lost when a patient becomes incompetent. Rather, surrogate decisionmakers such as a court-appointed conservator will have the legal authority to exercise the patient's rights in attempting to execute, the patient's wishes. There are three primary formal mechanisms available to the currently competent patient who, in anticipation of being incompetent, wishes to instruct surrogates about how to proceed. The first two involve the identification of the person who will serve as surrogate and the communication of directions to such a person. This may be accomplished in Connecticut through the creation of a durable power of attorney[2] or through advanced designation of a conservator.[3] The third involves the written communication of instructions through a document such as a "living will." The Connecticut legislature recently enacted a "death with dignity" statute which clarified the legal status of such documents in Connecticut. This statute signed into law by the Governor and will shortly take effect. Though imperfect, this legislation is potentially useful as a vehicle for expressing the wishes of a patient about future decisions.

Legislation of this variety has three major purposes: (1) to clarify the state's position with respect to the use of written, advanced directives; (2) to describe the form and process by which such directives can be made; and (3) to eliminate civil or criminal liability for those who in good faith seek to carry out the requirements of the statute.

The new Connecticut statute is similar to the legislation enacted in other states. Primary emphasis is placed upon removing fear of liability by describing the conditions under which the removal of a life support system from an incompetent patient shall not result in civil or criminal liability. There are four conditions:

> "(1) the decision to remove such life support system is based on the best medical judgment of the attending physician; (2) the attending physician deems the patient to be in a terminal condition; (3) the attending physician has obtained the informed consent of the next of kin, if known, or legal guardian, if any, of the patient prior to removal; and (4) the attending physician has considered the patient's wishes as expressed by the patient directly, through his next of kin or legal guardian, or in the form of a document executed in accordance with section 6 of this act, if any such document is presented to, or in the possession of, the attending physician at the time the decision to terminate a life support system is made."[4]

If the attending physician does not determine that the patient is in a terminal condition, defined as "the final stage of an incurable or irreversible medical condition which, in the opinion of the attending physician, will result in death,"[5] then beneficial medical treatment and nutrition and hydration must be provided. The statute does not apply to pregnant patients. It requires that comfort care and pain alleviation be provided in all cases. It states clearly that there is no presumption concerning the wishes of a person who has not executed a living will. The statute closes with a suggested form.

There are many problems with the statute. Requiring the consent of next of kin creates the possibility that the family may veto the wishes of the patient. Excluding pregnant patients creates practical and constitutional problems. The definitions and conceptualizations reflected in the statute raise a series of difficulties with respect to interpretation and application. These will be the subjects of next month's column.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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1. Schloendorff v Society of New York Hospital, 211 NY 125, 105 NE 92, 93, 1914.
2. See Connecticut General Statutes Sec 45-69o.
3. See Connecticut General Statutes Sec. 45-70.
4. Public Act No 95-606.
5. Ibid.

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Editorials

Psychiatric Issues in Medicine

This issue of *Connecticut Medicine* is devoted to current topics in psychiatry. As with other medical specialties, psychiatry is undergoing major changes, and each of these articles addresses a different aspect of contemporary practice. The authors are members of the medical staff of the Institute of Living in Hartford.

William L. Webb, Jr., the newly appointed Psychiatrist-in-Chief of the Institute, opens the issue with "The Psychiatric Hospital—A Challenge of Change and Survival," in which he presents a number of problems confronting psychiatry today. Some of them have resulted from current trends in American society in general or health care delivery in particular; other problems are longstanding. All are critical to the future of psychiatry. Dr. Webb has achieved prominence as an educator, medical administrator and liaison consultation psychiatrist. He holds office in several national professional organizations and is the author of a number of scientific publications.

The second article presents an explanatory review of psychiatric diagnosis based on the *Diagnostic and Statistical Manual of Mental Disorders.* Although in use for nearly five years, many clinicians remain unfamiliar with this diagnostic approach. The author, Frank W. Knoblauch, a staff psychiatrist at the Institute, is interested in nosology and data-based diagnostic systems.

The third article is an update of psychopharmacologic treatments for depression. Although many depressions are responsive to chemotherapy, a number of studies have shown that a large percentage of depressed patients do not receive appropriate pharmacologic treatment. This accentuates the need for continuing medical education particularly in such a rapidly changing field. Wayne Creelman frequently lectures to medical groups in the state and is co-author of the forthcoming handbook, *Psychotropic Drug Interactions.* John W. Goethe, co-author of this article and Director of Clinical Research at the Institute, is coordinating a large study of patients' response to treatment.

The complexity of psychiatric illnesses can hinder recognition of pathology. Systematic assessment is necessary in evaluating a patient's need for psychiatric referral. This process, referred to in the fourth article as "psychiatric triage," is essential if emotional illnesses are to be identified and adequately treated. Charles Boren, Medical Director of the Institute, and his co-author, Peter Zeman, Director of Psychiatric Education, have had extensive experience in consultation and education.

Even though the current trend is toward shorter periods of hospitalization, a substantial number of severely ill psychiatric patients require extended inpatient treatment. Richard Bridburg, Director of Admissions at the Institute, is a specialist in intensive hospital treatment, and his article highlights some of the very specialized aspects of this therapeutic approach.

One of the most rapidly expanding areas in health care is geriatric medicine. Psychiatry has developed a number of subspecialties in recent years, and, as illustrated in the article on geriatric psychiatry, there is now an important role for subspecialists as well as general psychiatrists. Walter A. Keckich, a geriatric psychiatrist and Division Director of Acute and Ambulatory Services at the Institute, has published a number of papers on psychiatric problems in the elderly. Harry E. Morgan, his co-author, is Director of Psychogeriatric Services at the Institute.

A variety of economic, social and political issues now confront the entire health care field. Thomas J. Conklin, Director, Program for Impaired Professionals, concludes this issue with a discussion of the impact of these forces on psychiatry. The theme of change and survival introduced in Dr. Webb's editorial, is reiterated in Dr. Conklin's review of the history of psychiatric institutions in Connecticut and their contemporary problems.

The diversity of topics in this issue reflects the breadth

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

of psychiatric practice and the recognition of the complex challenges facing today's providers of psychiatric care. The Institute of Living continues its commitment to traditional therapies while at the same time is utilizing its resources and expertise to explore new strategies in order to meet these challenges.

Jane Archer, Research Coordinator, and Helen Lansberg, Director, Medical Library, assisted in editing the manuscripts in this edition. Marcia Gerulaitis and Mary Ann Goodell of the Department of Research provided typing and prepared the tables.

John W. Goethe, M.D.,
and
Wayne Creelman, M.D.,
Guest Editors

The Private Psychiatric Hospital—A Challenge of Change and Survival

The opportunity for staff members of the Institute of Living to contribute to this issue of *Connecticut Medicine* is very timely. At the same moment that important advances are happening in psychiatry, the delivery of psychiatric care is undergoing critical and threatening changes. Having the staff from a single psychiatric hospital as contributors gives a blueprint of the diverse issues facing the delivery of modern psychiatric care.

Traditionally the psychiatric hospitals in the United States have filled a social as well as a therapeutic need. The Institute of Living was established in 1822 by the Connecticut State Medical Society in response to the perceived neglect of the mentally ill. Since then it has flourished as one of the preeminent national and international psychiatric hospitals. Established on the principle of moral treatment it has offered a therapeutic hope to the severely impaired. Often operating as a court of last resort for those who have not responded to treatment elsewhere, it has provided predominantly long-term hospitalization. Patients would commonly remain in the hospital for months or years treated intensely with psychotherapy. This basic therapeutic approach is currently under serious financial strain and the challenge is to evolve into a new system of care that will preserve the important continuity of the doctor/patient relationship. The obvious direction is toward a multi-therapeutic psychiatric center with a variety of ambulatory and residential treatment services. Accomplishing this under the rigorous scrutiny of regulatory bodies and the restrictions of the Connecticut State Commission on Hospitals and Health Care will be extremely treacherous. Many elements of such a system of care including halfway houses, residential treatment facilities and supervised apartments are not covered under current reimbursement plans. The emphasis has been entirely on reducing hospital stay but little or no attention has been paid to ambulatory care. These issues are carefully reviewed in Dr. Thomas Conklin's article.

During the past 30 years psychiatry has made a number of critical advances that have brought the specialty back into the mainstream of medicine. These include the advances in pharmacotherapy, improved clinical therapies, improved diagnosis and neurobiological research. With advances in neuroendocrinology, brain imaging, identification of multiple neurotransmitters, and brain mapping with electroencephalography a better understanding of the relationship of brain function and behavior is emerging. Advances in psychoanalytic research, group dynamics, cognitive and behavioral therapies and family therapy offer a broader spectrum of psychotherapeutic interventions. Combining a broader more flexible therapeutic armamentarium with more precise and careful diagnosis has clearly advanced our capacity to treat mental illness more definitively. Subspecialization into child and adolescent, geriatric, psychoanalytic and forensic psychiatry is currently a strong trend. The psychiatrist is at home in many clinical settings—general hospital, court, nursing home and ambulatory settings. The traditional jokes about psychiatrists involving the couch in private office settings seem increasingly dated. Many of these trends are illustrated in the range of subjects addressed by our authors.

Despite these advances psychiatry is still in its infancy as a science and, as Dr. Bridburg points out, at least 20% of our patients remain chronically ill. It is this population that poses the greatest challenge and problems for the psychiatric hospital. In the massive efforts to control medical costs these are the patients who are lost and forgotten. Visit any of our public facilities in our large cities and the message is clear. The very conditions that inspired the origins of the Institute of Living in 1822 exist today. The chronically mentally ill have been abandoned to the streets and public facilities of our major cities. The Institute of Living has faced many crises over the past one hundred and sixty-three years. On a number of occasions the very existence of the institution was threatened. Yet none are more serious than the problems facing the institution in 1985. It must not be driven to abandon its therapeutic traditions that have made it a resource over the years. The current trend toward brief hospitalization and discharge overlooks a segment of the psychiatric population that clearly benefits from longer stay in the hospital. This is spelled out in Dr. Bridburg's article. At the same time it must offer a wide spectrum of therapies to meet the increasing complexity of psychiatric diagnosis and treatment. The day of one all-encompassing therapy for all conditions is past.

The future of psychiatry and the Institute is intimately linked to research discoveries. Research in psychiatry has entered a new age of systematic inquiry. The new diagnostic system described by Dr. Knoblauch has allowed for the first time the identification of diagnostically replicable groups of patients. With the new developments in neurobiological research we stand on the threshold of understanding a whole new dimension of brain-behavior relationships. Traditionally the Institute has maintained a strong educational and research mission. The key to the Institute's future lies in strengthening our research mission. This is difficult in a time of shrinking public and private resources. New sources of support for research must be identified. An atmosphere of inquiry and education can be augmented by fostering affiliations with academic centers.

The modern psychiatric hospital continues to be a center of psychiatric treatment, education, and research. However, clearly these activities are shifting into a new configuration in which the hospital becomes part of a comprehensive system of care. Financial resources continue to shrink and the quality of care may be compromised by the constant pressure for cost containment. The challenge is to continue a tradition of excellence and service to Connecticut in a time when major change is underway and the survival of key elements of psychiatric care may be under threat.

William L. Webb, Jr., M.D.
Psychiatrist-in-chief,
Institute of Living, Hartford, CT

Harmful Ticks in Our Backyard

The public generally assumes that a tick is about the size of a pea, with eight legs. This is, indeed, the common dog-tick—in Connecticut only rarely infected with Rocky Mountain Spotted Fever (RMSF), and relatively harmless. The other species—the deer-tick which transmits Lyme Disease—has become a much greater menace. It is tiny, about the size of a sesame seed. Because it is so small, it is seldom noticed or searched for. In examining children after they've roamed the woods, people usually look for the large dog tick.

The conventional terms of "dog-" and "deer-tick" are not too meaningful. Both types feast on any mammal they can reach. The small deer tick is found not only on deer, but also on raccoons, mice, squirrels and dogs, and on a wide variety of Connecticut birds, which may account for the rapidly spreading disease it carries. The increase in the number of cases of reported Lyme disease is due only in part to the fact that physicians are becoming more aware of it; the number of infected ticks is actually increasing and the endemic area of Lyme Disease is expanding rapidly.

Lyme disease is not a new disease. Erythema chronicum migrans (ECM) was reported from Sweden over 70 years ago, and chronic meningitis associated with ECM was described in Europe in 1930. The early studies in Eastern Connecticut, in the Lyme area, were made be Steere and his coworkers at Yale. Much of the original lab and field work that followed the clinical studies was carried out at the Connecticut Agricultural Experiment Station, particularly by Magnarelli and Anderson.

A spirochaete has been found from ECM in Europe, and a similar or identical spirochaete has been grown from blood, skin lesions or cerebrospinal fluid from patients with Lyme disease. This spirochaetal species belongs to the genus Borrelia which causes louse-borne and tick-borne relapsing fever in many parts of the world.

Lyme disease is a multisystem disorder. It may variously affect skin, joints, heart and nervous system. Most common and characteristic are joint and skin disorders. The neurological abnormalities vary greatly and correspond to what has been reported from Europe as meningo-polyneuritis.

Bites from infected deer ticks may at first (after days or weeks) produce the erythema migrans. This begins as a small red macula which enlarges, with a wide red margin and some central clearing. It lasts about 3 weeks. Less than half the patients show the skin lesion as an early manifestation of the infection and few patients can recall being bitten by a tick. A few weeks after the erythema or without evidence of it, the prominent symptom is arthritis; cardiological and a variety of neurological abnormalities may follow. Malaise, headaches, fatigue, chills and fever usually accompany the other manifestations, and despite antibiotic treatment, symptoms, particularly those affecting joints, can continue for many months or even years.

Since the disease affects many systems, no specific symptoms can be found in all cases. Large joints may show painful swelling, with a mean duration of eight days, and relapses that occur months later. The other symptoms, such as myocardial conduction defects, cranial nerve palsies, and meningitis occur less frequently. Serological response (1:128 or higher) help in confirming a suspected diagnosis.

Cases of Lyme disease are found from Spring to late Fall, but they peak in the summer and early Fall. This diagnosis should be suspected in patients with obscure, subacute arthritic, cardiological and neurological disorders of uncertain origin.

One can only speculate how the infected ticks first came to the Lyme area of Connecticut. Their origin is still a mystery: they may have been carried by some aberrant birds that somehow made it across the Atlantic to North-East Connecticut.

Early diagnosis is important in both tick-borne infections, R.M.S.F. and Lyme disease, because prompt antibiotic treatment favorably affects the course of the disease. While there are hundreds of cases of Lyme disease per year, and a high percentage of the deer-tick is infected in some areas, R.M.S.F. remains very rare in Connecticut. The rash of R.M.S.F. is more petechial and widespread than the erythema of Lyme disease. The onset is more sudden and the symptoms of chills, malaise and fever are more severe. The agent causing this tick-borne infection is a Rickettsia. The season of its occurrences is the same as that of Lyme disease.

Walking past tall grasses or brush, particularly in scrubby woodland in infested areas, one runs the risk of picking up either dog-ticks or the tiny black-legged, fast moving deer-ticks. The ticks are usually on the tips of vegetation, grasses, leaves and shrubbs, waiting for any warm-blooded host for their long meals. People acquire them from brushing against plants, at which time the ticks grab and hold on to clothing (or the fur of household pets.) To prevent infection, it is advisable to wear long pants and shirt sleeves, to tuck pants into the socks at the ankle, to use insect repellents, which are of limited effectiveness, and to shower after work or play in the woods. In densely wooded areas it may be advisable to wear a hat sprayed with insect repellent to avoid attracting the ticks which may fall from bushes onto the head particularly of children.

Hans H. Neumann, M.D.

Wilton, CT

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Tufts University Medical School

Metabolic Myopathies

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Columbia Presbyterian Medical Ctr.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

MEDICAL PROFESSIONAL LIABILITY

To the Editor: The AMA reports in the July issue of *Connecticut Medicine* that malpractice claims and insurance premiums are on the increase and that physicians are practicing more defensive medicine to minimize their risks. *That is all true, obviously.*

But when reading the article, one gets the impression that physicians are motivated to defensive medicine primarily because of the *financial risks* involved. Though the financial risks are real and a worry to everyone, there is also a very real *personal risk* that was not mentioned. And that is the *travail of unnecessary publicity* which a claim can engender. Such adverse publicity often borders on *ostracism* and can have serious personal repercussions for both the doctor and his family.

The AMA report is useful but it is *incomplete* and can mislead those political bodies involved with making health care policy. The AMA Center for Health Policy Research would do well to consider all the motivating factors behind defensive medicine if appropriate conclusions are to be drawn from our malpractice experience.

Edward J. Volpintesta, M.D.

Special Notices

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ELLA T. GRASSO MEMORIAL CONFERENCE
November 20, 1985

This symposium addresses clinical problems in gynecologic oncology and is directed toward obstetricians/gynecologists, medical oncologists, radiation therapists, pathologists, nurses and residents. Sponsored by the Divisions of Gynecologic Oncology at the Yale University School of Medicine and the University of Connecticut School of Medicine with the Yale Comprehensive Cancer Center.

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Ella T. Grasso, 83rd Governor of Connecticut, the first woman elected Governor without succeeding her husband, died of ovarian cancer. "This unique woman, a distinctive Governor, was the inspiration for this living tribute," stated Peter Schwartz, M.D., Chairman of the conference. "The Ella T. Grasso Memorial Conference will continue to be outstanding, the state of the art in research as well as clinical management." Early commitment is suggested for this important event.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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Opportunity available in our 220-bed community hospital with an active prehospital care program for a full time emergency medicine trained or practice tract prepared physician. Our six full time physician staffed department has a volume of 28,000 visits annually. Excellent benefits and competitive salary are offered. Please send CV to Patricia C. Kuszler, M.D., Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT 06450.

Connecticut—Full time Emergency Medicine Physician, emergency medicine experience and ACLS certification required; patient volume 28,000 visits annually. Write Don Rankin, M.D., Chairman, Department of Emergency Medicine, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604.

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B/C or B/E Family physician for young progressive group practice in Western Connecticut. Highly desirable area. Send CV to: Brookfield Family Medicine Center, 940 Federal Rd., Brookfield, CT 06804.

Board certified or eligible residency trained family physician wanted to associate with same in a growing town of 20,000 in the foothills of the Connecticut Berkshires. Established, growing practice—salaried first year; full partnership in second year. No OB. Send CV to P. Anderson, M.D., One Old Park Lane, New Milford, CT 06776.

Family physician to join board certified residency trained family practitioner in a growing, two office practice in Guilford or Essex on the shoreline. Beautiful area; enjoyable life style; excellent schools. Great opportunity for professional and personal satisfaction. Will consider part-time. Reply to, Alan Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

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Southern CT area/Walk-In Medical Center seeks licensed physicians. Full and part time positions available days, evenings and weekends. Competitive salary. Please respond to CSMS, GP/JS.

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INSTITUTIONAL MEDICINE

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Walk-In Medical Services is seeking full and part time physicians to work in a convenience medical facility in Orange, CT. FAM. PRAC/IM preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Internist wanted to join group of three busy internists. Rural community with two universities in eastern Conn. 150-bed hospital. Send CV to Internal Medicine Group, 14 Quarry St., Willimantic, CT 06226.

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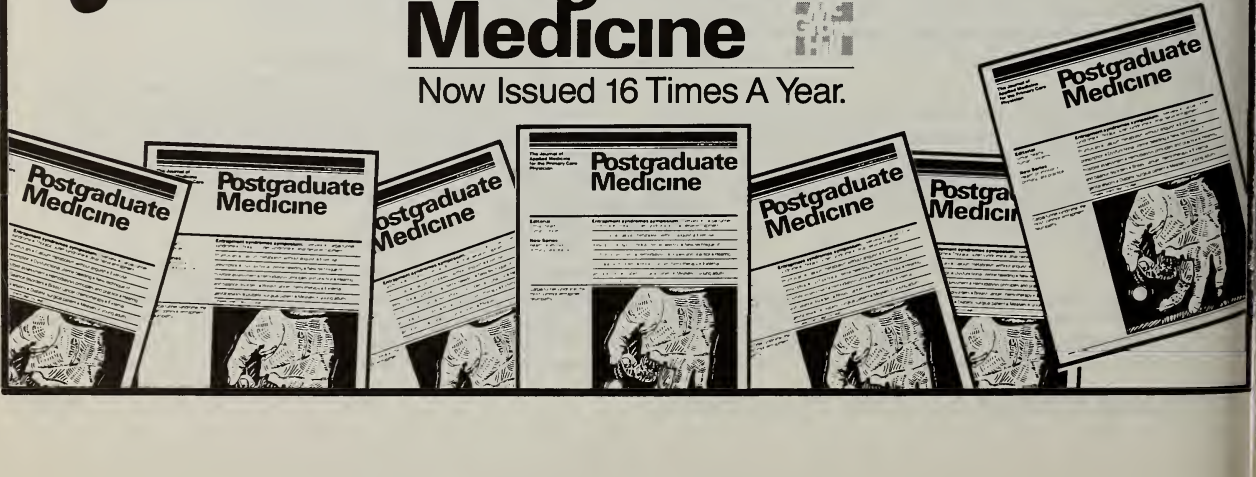

Update on the Treatment of Parkinson's Disease

DIANE WIRZ, M.D.

ABSTRACT – Levodopa has dramatically improved the outlook for patients with Parkinson's disease but it is symptomatic therapy and is associated with the problems of loss of efficacy, clinical fluctuation, and toxicity. Amantadine and anticholinergics are useful for some patients with mild, early Parkinson's disease. Bromocriptine is the only direct dopamine receptor agonist approved for use in Parkinson's disease in the United States. It appears to be especially useful in smoothing out clinical fluctuations. The role direct dopamine receptor agonists will play in the treatment of early Parkinson's disease is still unclear. These drugs have significant psychiatric side effects and are expensive. Levodopa is most effective during the first three years of treatment. It may hasten the progression of the disease. Therefore, it is recommended the introduction of levodopa is delayed as long as possible and the dose is kept low. Each patient must be individually considered. Some patients may need early therapy to keep their jobs or for psychological well-being. A hope for the future is fetal nigral transplants.

Parkinsonism is a syndrome consisting of at least two of the four cardinal signs: rigidity, tremor at rest, bradykinesia, and loss of postural reflexes.[1] The bradykinesia is manifested by masked facies, decreased blinking (sometimes alternating with blepharospasm), decreased swallowing with drooling of saliva, hypophonia, decreased rapid succession movements, short stepped gait, decreased arm swing when walking, and slowness in carrying out daily activities.[1] The most common cause of parkinsonism is idiopathic Parkinson's disease, first described in 1817 by James Parkinson in the classic monograph, "An Essay on the Shaking Palsy." Parkinson's disease is a degenerative disorder that causes the motor symptoms of parkinsonism and is also associated with dementia, depression, and subjective sensory symptoms.[2] In Parkinson's disease there is a reduction of brain dopamine, norepinephrine, and serotonin.[1] Many of the clinical features of Parkinson's disease, are caused by neostriatal dopamine deficiency. Norepinephrine deficiency may be associated with gait apraxia or "freezing".[3] It is not known what symptoms are correlated with the serontin deficiency in Parkinson's disease.

Before levodopa therapy, individuals with Parkinson's disease died at a three times greater rate than their age-matched controls.[4] The mortality was the same in the 1960's as it was at the turn of the century in spite of the use of anticholinergics and sterotaxic surgery.[4] By 1978 patients treated with levodopa plus other good therapies were living almost as long as their age-matched controls.[5] This marked reduction in mortality is largely due to improved ambulation, and reduced incidence of pneumonia, pulmonary emboli, decubiti, and other complications of immobility.[6] Unfortunately, present day treatment is only symptomatic. It does not slow down the progressive loss of nigral and striatal neurons.[6] This paper will outline the modern treatment of Parkinson's disease.

Levodopa

One of the most significant breakthroughs in modern neurology was the introduction of levodopa in the treatment of Parkinson's disease. In 1960 Ehringer and Hornykiewicz discovered neostriatal dopamine deficiency in Parkinson's disease.[7] Cotzias, Van Woert, and Schiffer in 1967 used large doses of D, L-dopa (3-16 grams) in sixteen patients. Eight patients had marked improvement and two patients had moderate improvement.[7] Subsequently, pure L-dopa instead of the racemic mixture is used, since this form is the active precursor of

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DIANE WIRZ, M.D., Chief Resident in Neurology, Department of Neurology, University of Connecticut Health Center, Farmington, CT.

dopamine.[7] Levodopa significantly initially improves 75% of patients with Parkinson's disease.[8]

Levodopa is rapidly absorbed from the small bowel by an active aromatic amino acid transport system. Peak serum concentrations occur 0.5 to 2 hours after an oral dose and the plasma half-life is 1 to 3 hours. Absorption is dependent on gastric emptying, pH of gastric juice, and competition for absorption sites by concomitantly administered large oral amino acid loads. Intravenous levodopa is available for investigational use only.

Dopa decarboxylase inhibitors, such as carbidopa, enhance levodopa's potency and decrease the peripheral side effects such as vomiting, hypotension, and arrhythmias. The plasma level of levodopa is increased because the breakdown in the periphery is inhibited. These higher levels enhance the entry of levodopa into the brain.[7] Carbidopa does not cross the blood brain barrier. Therefore, it does not inhibit brain decarboxylase which converts levodopa to dopamine.[8] Patients require only about one quarter the dose of levodopa when it is combined with a dopa decarboxylase inhibitor. However, the effective plasma half-life of levodopa is not prolonged.[1] The increase in central potency is usually desirable but there may be an increase in central adverse effects such as dyskinesias and mental changes.[7]

Soon after the introduction of levodopa for the treatment of Parkinson's disease, significant problems appeared. The following is a discussion of some of the problems associated with chronic levodopa therapy.

Failure of Initial Therapy

Some patients seem to fail to respond to levodopa simply because the dose is insufficient. Dosage must be individualized. Occasional patients will experience benefit only when much higher doses than the usual 750-1000 mg per day of levodopa are used.[9] For this reason, if a patient shows little or no response to an average dose of Sinemet and shows no dyskinesias or other side effects the dose should be increased. The end point should be a therapeutic response or dose-limiting side effect.[9]

Other patients may fail to respond to levodopa because they are taking another drug that interferes with levodopa's action. Most commonly this is due to simultaneous treatment with a dopamine receptor blocking agent such as a phenothiazine.[9] Papaverine given to "improve cerebral circulation" may block the effect of levodopa.[9] Pyridoxine reverses L-dopa effect. This is not usually a problem if the patient is on carbidopa unless very large doses of pyridoxine are being taken.[10]

It is appropriate to question the diagnosis of Parkinson's disease if the patient does not respond to levodopa. A number of Parkinsonian syndromes such as striatonigral degeneration, progressive supranuclear palsy, olivopontocerebellar atrophy, and arteriosclerotic 'pseudo-parkinsonism' may be misdiagnosed as Parkinson's disease.[9] Although these diseases differ pathologically from Parkinson's disease, they may appear similar in their early stages. These syndromes respond poorly to anti-parkinsonian agents.[10]

Loss of Efficacy with Duration of Therapy

Regardless of the duration of the disease, the best results are achieved in the first few years of levodopa therapy. The critical observation is the benefit derived from levodopa begins to decrease after three years of treatment regardless of the extent of therapeutic response or severity of disease when levodopa was started.

Even with treatment, Parkinson's disease progresses. This factor alone probably accounts for some of the loss of effectiveness of levodopa. However, could levodopa be responsible in part for this deterioration? If levodopa accelerates the progression of Parkinson's disease it would be best to delay the introduction of levodopa in a patient for as long as possible. A study by Diamond and Markham suggested that the loss of efficacy paralleled the worsening of Parkinson's disease which would have occurred without treatment.[11] They suggest introducing levodopa therapy early in the disease. Stanley Fahn feels there are several flaws in Markham and Diamond's study. He notes their findings make it difficult to explain why drug holidays work.[1] Lesser and his associates in a retrospective study found the duration of treatment was a more important factor in the loss of efficacy to levodopa than duration of illness.[12] In light of the above findings, Fahn recommends delaying introducing levodopa until the drug is definitely needed and not attempting 100% relief of symptoms if this requires high dosage.[7]

Clinical Fluctuation

The development of clinical fluctuation is found in 87% of patients treated for 10 years.[6] There are two forms of fluctuations. The wearing-off phenomenon represents a pharmacokinetic problem.[7] The "off" period coincides with low plasma levels of levodopa.[7] This requires more frequent administration. Sometimes it is effective to supplement with direct acting dopamine agonists which have a longer half-life.[13]

The 'on-off' phenomenon is even more difficult to ameliorate. It is sudden and random in onset (as though someone flipped on a light switch) and is not associated with low levels of levodopa. This may be a pharmacodynamic problem due to the receptors being altered suddenly to an allosteric inactive state.[1]

Nutt, et al suggested in a recent article in the New England Journal of Medicine that interference of absorption of levodopa by food and competition between levodopa and neutral amino acids for transport from plasma to brain may be partially responsible for the fluctuations seen in patients with Parkinson's disease.[14] These findings provide a basis to attempt dietary manipulation in patients with severe 'on-off' phenomenon. Lithium carbonate has been reported to be useful in treating the 'on-off' effect but this somewhat controversial.[15]

Another way of dealing with 'on-off' oscillations, decreased responsiveness, and toxic effects of levodopa is to give the patient a "drug holiday," as first proposed by Sweet. Patients may remain more sensitive to levodopa with fewer side effects for six months to a year after the holiday. However, the holiday requires hospitalization and excellent medical and nursing care. Many patients become akinetic, rigid, bed-ridden, unable to turn, speak, or swallow.[8] Violent resting tremors may cause hyperthermia and rhabdomyolysis. They become subject to all the hazards of immobility including pulmonary embolism, aspiration pneumonia, urinary tract infection, and decubiti. Both the patient and family are often alarmed when they see the severity of the underlying Parkinson's disease. Many experts feel the benefits of the full holiday are not worth the risks. A modified short holiday (one to two days off levodopa) is less risky and may be as effective.[1]

Limitations Due to Toxicity

Since the introduction of carbidopa, the most common dose-limiting adverse effects are central in origin—dyskinesias, psychiatric problems, and altered sleep-cycle disturbance.[1] Peak dose dyskinesias are manifested as abnormal movements in the hands, arms, legs, and face.[6] They usually begin one to two hours after a dose of levodopa and last minutes to hours.[7] One way to deal with this problem is to increase the frequency of drug administration and to decrease each dose.[6] Interestingly, most patients state they prefer the dyskinesias to the symptoms of parkinsonism.[6]

Psychiatric symptoms and sleep disturbance occur in more than one half of the patients on levodopa for two or more years. Often there is a progression of symptomatology from sleep disruptions to striking dreams, to hallucinations, and then to a confusional state.[16]

Dementia commonly occurs in patients with Parkinson's disease. It is unclear whether levodopa accelerates the development of dementia.[2] Suggestions for managing parkinsonism in the presence of psychiatric symptoms and/or dementia are outlined in Table 1.

Table 1

TREATMENT OF PARKINSON'S DISEASE IN THE PATIENT WITH PSYCHIATRIC SYMPTOMS AND/OR DEMENTIA[16]

1. discontinue anticholinergics and amantadine
2. avoid bromocriptine
3. lower the dose of levodopa
4. consider drug holiday for psychiatric symptoms
5. may need to resort to neuroleptics

A significant number of patients with Parkinson's disease are depressed.[16] Tricyclic and tetracyclic antidepressants may be used but they may exacerbate hallucinations. Electroconvulsive therapy is not contraindicated in Parkinson's disease and there is even some preliminary evidence that it may improve the parkinsonism, independent of the depression.[16]

Early morning dystonia appears to occur when the plasma level of levodopa is low and the patient is in an "off" state.[7] The patient has painful flexion or extension of the toes. Some patients respond to the administration of a dopamine agonist at bedtime, since the half-life is longer.[13] It has been reported that the administration of 10-40 mg of Baclofen at bedtime will ameliorate this symptom.[6]

Autoimmune hemolytic anemia has been reported in patients on levodopa.[10] It is felt the mechanism is comparable to that occurring with methyldopa therapy. About 10 percent of patients on levodopa develop a positive Coomb's test.[10]

Another concern is that the chronic use of levodopa may stimulate the growth of melanomas. Levodopa is contra-indicated in patients with a history of melanoma.

Other Medications Used In Parkinson's Disease

Anticholinergics

The anticholinergic drugs are useful for some patients with early, mild Parkinson's disease. Dopamine terminals in the stritum make synaptic contact with striatal acetylcholine neurons. The lack of dopaminergic influence in Parkinson's disease disinhibits cholinergic neurons. Anticholinergic drugs are felt to restore the balance.[1] Cautious administration is necessary to avoid annoying and dangerous side effects. The most commonly encountered side effects are dryness of the mouth, blurred vision, urinary retention, constipation, and psychiatric disturbance. The mental effects can be significant and include confusion, impairment of memory, and psychosis.[10] These mental changes are more common in older patients.[10]

Amantadine

Amantadine is another medication that can be used in early, mild Parkinson's disease. It is felt to have both an anticholinergic and dopaminergic action.[1] Amantadine appears to activate the release of presynaptically stored dopamine. Most patients respond to it for only a short period. The 'fall off' effect can be explained on the basis of a lack of sufficient presynaptic stores of dopamine.[1] Some experts feel that the patient can continue to benefit from amantadine if levodopa is added but others disagree. Amantadine has many of the same side effects as the anticholinergics, including the mental effects. An additional problem with amantadine is the development of livido reticularis, commonly in women during the first six months of therapy.

MAO-inhibitor-Deprenyl

Dopamine is metabolized by monoamine oxidase (MAO) type B.[7] Deprenyl, a type B MAO inhibitor has been used experimentally to treat Parkinson's disease.[1] There is no "cheese effect" when deprenyl is given with levodopa.[1] Some studies suggest the drug may have a mild benefit in Parkinson's disease but this is controversial.[7]

Direct Dopamine Receptor Agonists

The problems associated with chronic Sinemet therapy has prompted investigators to search for new medications to use in parkinsonism. The theoretical advantages of a direct-acting dopamine receptor agonist are outlined in Table 2.

Table 2
THEORETICAL ADVANTAGES OF DIRECT ACTING DOPAMINE RECEPTOR AGONIST IN PARKINSON'S DISEASE [13]

1. a dopamine agonist is not dependent on the integrity of presynaptic dopamine neurons as is the case for lovodopa
2. there is no competition with dietary amino acids for intestinal absorption or transport across blood-brain barrier
3. a dopamine agonist may have a longer duration of action than levodopa
4. formulation of specific receptor agonists (D-1, D-2, etc.) might provide more specific therapeutic effects while avoiding some of the side effects
5. carbidopa would not be necessary
6. false transmitters from levodopa metabolites would not result

Apromorpine, an aprophine improves parkinsonian symptoms but it requires administration by injection and is limited by the side effects of nephrotoxicity and vomiting. [13,17]

The ergot drugs are being most intensively investigated for use in Parkinson's disease. In the United States bromocriptine is the only ergot derivative approved for use in parkinsonism. [13] Bromocriptine is almost completely absorbed from the gastrointestinal tract and peak plasma concentrations occur at 30-120 minutes. [17] High levels last 4 to 8 hours. [13] Bromocriptine is excreted in the bile and feces. Stern and Lees studied patients treated with bromocriptine alone with those treated with levodopa alone. They found bromocriptine therapy was rarely associated with dyskinesias or 'on-off' effects but, psychiatric side effects were more common. [18] Both bromocriptine and levodopa treated patients declined at the same rate. [18] Importantly, Pearce and Pearce found the psychiatric symptoms more serious than those with levodopa. [17] Bromocriptine produced a severe psychosis in which the patient became hostile and violent. [17] Complete withdrawal of bromocriptine often left the patient psychotic for one to three weeks. [17] Hypotension is often a problem with bromocriptine, especially during initiation of therapy. Erythromelalgia (burning, red, edematous feet), acrocyanosis, and digital vasospasm are other adverse effects reported with bromocriptine therapy. [13, 17] Domperidone, a blocker of peripheral dopamine receptors may lessen the peripheral adverse effects of the dopamine agonists. Paul Teychenne et al have suggested using low dose bromocriptine (average dose, 15 mg per day) to prevent some of the side effects. [19] Adverse effects and expense of bromocriptine are major drawbacks to its use. [13] Other dopamine agonists that have been investigated include lergotrile, lisuride, and pergolide. Lergotrile is no longer used because it is hepatotoxic. Lisuride is water-soluble and may be useful as a parenteral agent in the treatment of Parkinson's disease. Pergolide is a more potent dopamine agonist than bromocriptine and has an even longer duration of action (8-12 hours). Pergolide appears to have the same psychiatric side effects as bromocriptine.

Surgery

Prior to the introduction of levodopa surgery was used commonly in the treatment of Parkinson's disease. Sterotactic lesions were generally placed in the ventrolateral nucleus of the thalamus. Today surgery should only be considered for patients with disabling tremor or with severe levodopa-induced dyskinesia. [20] Surgery can only be done on one side.

Investigational Approaches

An exciting possibility involves the transplantation of adrenal or fetal nigral cells. This has been recently investigated in an animal model. Fetal dopaminergic cells were transplanted in an adult with an experimental lesion in the substantia nigra. [20] The transplanted cells corrected some of the behavioral disturbances. It may be possible to alleviate the clinical features of Parkinson's disease by grafting a patient's own adrenal cells into the brain.

The Approach to the Patient with Parkinson's Disease

The treatment of Parkinson's disease needs to be individualized. The goal is to keep the patient independent for as long as possble. It is crucial that the patient and the family become participants in the treatment. A helpful book to recommend is *Parkinson's Disease: A Guide for Patient and Family* by R.C. Duvoisin. A guide for initiating therapy is shown in Table 3.

Table 3
INITIATING TREATMENT IN PARKINSON'S DISEASE [1]

Group I—early Parkinson's disease with mild symptoms which only cause mild embarrassment or minimal inconvenience:
1. patient education
2. physical therapy
3. follow-up every 3 to 6 months

Group II—symptoms troublesome but not a threat to income, psychological well-being, or social relationships:
1. patient education
2. physical therapy
3. anticholinergics or amantadine

Group III—potent therapy must be used from onset either because of advanced disease or patient needs maximum amelioration of symptoms:
1. patient education
2. physical therapy
3. sinemet

When Sinemet becomes necessary for treatment, the dose should be kept as low as possible. Sinemet 25/100, three times a day is a good dose to start therapy. Unless the patient has problems with nausea, it is best to give the medication on an empty stomach. Levodopa is an amino acid and competes with other amino acids for transport across the intestinal mucosa and the blood brain barrier. [7, 14] Levodopa should be avoided at bedtime since it is not needed during sleep and it may cause vivid dreams and nightmares.[7] A bedtime dose may be needed if the patient becomes immobile and requires levodopa to go to the bathroom during the night. If the patient has an inadequate response to levodopa, or has complications, consideration can be given to adding a direct acting dopamine agonist.

If a patient on Sinemet requires surgery for another problem, levodopa should be continued until the last dose the evening before surgery and resumed as soon as possible after surgery. Generally, the post-operative course is much smoother if levodopa is resumed promptly.[10] Most patients suffer only partial recurrence of their symptoms during 24 hours off levodopa. Unfortunately, intravenous levodopa is not available for general use and rectal absorption of levodopa is unreliable.[10]

Conclusion

Modern therapy has improved the outlook for the patient with Parkinson's disease. However, treatment remains symptomatic and is associated with serious problems. A hope for the future is to find a way to replace the nigral and striatal neurons that are lost in the disease.

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BEHIND THE FACE OF HYPERTENSION

Continuing evidence for central control

Neodynium-Yag Laser and Cataract Surgery

ALAN L. STERN, M.D., DANIEL M. TAYLOR, M.D. AND RICHARD BERNSTEIN, B.S.

ABSTRACT–A new "non-thermal" laser, the Neodynium-Yag Laser, using the principle of optical breakdown, (ionizing breakdown) has now given physicians the ability to "cut" tissue under microscopic control. The ability of controlled, accessible, non-invasive cutting has revolutionized the therapy of secondary membrane formation, which often occurs after extracapsular cataract extraction. We have reviewed the first 125 YAG laser procedures done at the Grove Hill Clinic by the two senior authors.

Extracapsular cataract surgery leaves the posterior lens capsule intact and is presently the preferred method of cataract extraction. In approximately 50% of these eyes, a visually compromising secondary membrane develops along capsular remnants, requiring surgical intervention.[1] The Neodynium-Yag laser allows "cutting" of secondary membranes by a controlled, non-invasive office procedure. The YAG laser capsulotomy eliminates the expense, time and risks of in hospital surgical capsulotomy.[2]

Case Reports

Case 1: A 62-year-old female underwent an uncomplicated extracapsular cataract extraction with intraocular lens insertion (ECCE^{c}IOL) in January, 1981. Postoperatively, her best corrected visual acuity was 20/20. By September, 1982, her best corrected visual acuity had decreased to 20/70 from secondary membrane formation along the posterior capsule. She was admitted to New Britain General Hospital where a surgical capsulotomy with a Ziegler knife needle was performed under local anesthesia. Postoperatively, her visual acuity returned to 20/20.

Case 2: A 69-year-old female underwent ECCE^{c}IOL insertion in May, 1982. Her best corrected vision postoperatively was 20/25. By September, 1984, she developed a secondary membrane with a visual acuity of 20/60. A YAG laser capsulotomy was performed in the office with a return of 20/25 acuity. See Figure 1.

Methods and Results

We have retrospectively reviewed the initial 125 cases of YAG laser capsulotomy done by two of the authors, ALS and DMT, using the American Medical Optics Q switched Neodynium YAG laser. The patients ranged in age from 38 to 84. The time from original cataract surgery to laser capsulotomy ranged from 2 months to 69 months. The mean time from surgery to capsulotomy was 24 months. Pre-laser visual acuities ranged from 20/50 to finger counting. (See Table 1). Forty-seven patients had pre-laser acuities of 20/50 to 20/70, of those, 43 patients improved to 20/40 or better. Four had no improvement. No patient of the first 125 patients followed at the three month level lost visual acuity post laser. Sixty patients had a pre-laser visual acuity range of 20/80 to 20/200. Of the 18 patients with pre-laser acuity of 20/300 to hand motions, 10 patients improved to 20/40 or better and three had no improvement. Five patients improved but not to the 20/40 level. The power range of the YAG laser was 0.9 to 2.1 millijoules with 90% of the capsulotomies performed between 1.2 and 1.6 millijoules. The mean number of pulses was 18 and the number of pulses need-

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ALAN L. STERN, M.D., Assistant Clinical Professor, University of Connecticut School of Medicine, Farmington, CT; Attending, New Britain General Hospital, New Britain, CT. DANIEL M. TAYLOR, M.D., Clinical Professor, University of Connecticut School of Medicine; Senior attending, New Britain General Hospital. RICHARD BERNSTEIN, B.S., Medical Student, University of Connecticut School of Medicine.

Table 1

PREOPERATIVE ACUITY		POSTOPERATIVE ACUITY	POSTOPERATIVE ACUITY	NO IMPROVEMENT
		20/40 or better	improved but less than 20/40	
20/50-20/70	47	43	1	3
20/80-20/200	60	50	7	3
20/300 to Hand Movements	18	10	4	4
Total	125	103	12	10

ed to reach a satisfactory opening tended to decrease with continued experience with the laser. An intraocular lens was present in 114 of these first 125 cases. An intraocular lens can be marred by malfocusing of the laser and unplanned pitting of the intraocular lens was noted in four cases and did not adversely effect the postoperative result. The intraocular pressure was measured postoperatively at 24 hours and one week for all 125 patients. A pressure rise of 5 mm. of mercury or more was noted in 21 patients. These patients were treated with ocular hypertensive medications and no patients required these medications longer than seven days. The intraocular pressure rise was not predictable and did not correlate with either the number of pulses, the energy level, or the preoperative intraocular pressure.

Discussion

An intracapsular cataract extraction (removal of the entire lens and capsule) avoids the inconvenience of secondary membrane formation following cataract extraction. However, extracapsular cataract extraction provides multiple advantages over intracapsular cataract extraction. Extracapsular cataract extraction provides a stronger internal integrity to the eye following fixation of a posterior chamber intraocular lens. Extracapsular cataract extraction decreases the complications of retinal detachment[3] and decreases the incidence of complications related to intraocular inflammation such as macular edema and corneal decompensation.[4] These advantages outweigh the annoyance of secondary membrane formation.

The Neodynium YAG laser is an extremely high energy laser used for nano and picosecond intervals and narrowly focused to cause optical breakdown of the tissue. Such high energy release causes a small plasma state to evolve with resultant fracture of material. Because of these properties, it is uniquely applicable for posterior capsulotomies. Modern YAG lasers for use in ophthalmology have delivery systems through conventional slit lamps (See Figure 2). This allows convenient "in office" microlaser surgery avoiding or decreasing the complications of more invasive intraocular surgery which includes infection, bleeding and inflammation.

One hundred and three of these 125 patients in this study improved their visual acuity to 20/40 or better via this technique. The improvements in vision have been stable with no evidence of loss of visual acuity with up to a year followup. There was no incidence of decreased visual acuity and no complications other than a mild increase in ocular pressure in 17% of the patients. Reasons for no improvement in vision include other complicating intraocular factors such as preoperative optic atrophy, preoperative macular pathology and preoperative amblyopia.

With the obvious advantages of the YAG laser capsulotomy over other alternatives, the FDA has recently approved the YAG laser as effective and safe for posterior capsulotomy. Other uses of the Neodynium YAG laser in ophthalmology are presently under investigation and include iridectomy, trabeculoplasty, lysis of synechia and lysis of vitreous membranes.[5]

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Survey of Handicapped Physicians in Practice

RIF S. EL-MALLAKH, M.D.

ABSTRACT—A preliminary survey of practicing physicians in neurology, pathology, and psychiatry was conducted. It was found that 1.12% of all physicians in this sample possessed a physical handicap. The severity of these handicaps ranged from blindness to impaired hearing. In this preliminary survey handicapped residents appeared predominantly in programs with handicapped faculty members, indicating that role models may play an important role for the young handicapped doctor.

Aside from occasional anecdotal reports of practicing physicially handicapped physicians,[1,2] there is very little known about practicing handicapped physicians (personal communication, Zondolo, F., Coordinator, Disabled Physician Listing, St. Paul, Minnesota, September 16, 1983). There exists a relatively larger body of knowledge on alcoholism and drug abuse among physicians, but this, too, is insufficient.[3] This project was undertaken to improve understanding of the role of practicing physicially handicapped physicians.

Materials and Methods

A short questionnaire and cover letter, and a stamped, self-addressed envelope were mailed to 66 departments with residency programs. The first 22 departments, as listed alphabetically in the 1983/84 Directory of Residency Training Programs,[4] in the fields of neurology, pathology, and psychiatry, were selected.

Project Design

The fields selected were: neurology, since neurologists deal daily with handicapped persons; pathology, because of the lack of patient contact, and the less rigorous work day may make it easier for a handicapped physician to practice; and psychiatry, again because the mode of practice tends to be less physically rigorous in nature.

Only departments with residency programs were selected, for two reasons. First, it was believed that academic programs may attract physicians who are disabled, and second, to determine if programs with handicapped faculty members tended to select or attract handicapped residents.

The choice for an alphabetical selection of programs was initially made so that the sample would be "random." Unexpectedly, this method introduced a geographical bias into the survey.

The questionnaire was designed to be easy and quick to fill out. The major problem with the questionnaire was the wide definition of "handicap." This became particularly evident when one respondent (not included in the data presented here) reported that all 15 faculty members and 21 residents were handicapped, and proceeded to list visual deficits, headaches, pulmonary disorders, obesity, eating disorders, sleep disorders, back aches, etc.

Results

The overall response rate was 53%. All three fields responded at a similar rate: of the 22 departments queried in each field, 14 in pathology, 12 in neurology, and 9 in psychiatry responded. The geographical distribution of responding departments was also of interest. Seven states were included in the survey. None of the seven departments in Alabama responded, whereas in the remaining states there appeared no difference in the rate of responses (Arizona 4/8, Arkansas 2/4, California 26/42, Colorado 1/1, Connecticut 1/2, Washington DC 1/2).

Of the 888 physicians in this survey, 11 had some type of handicap (Table 1). There were more handicapped faculty members (8) than residents (3). Neurology contained the fewest number of handicapped physicians (1/247); whereas pathology and psychiatry contained

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RIF S. EL-MALLAKH, M.D., Resident in Neurology, Department of Neurology, University of Connecticut School of Medicine, Farmington, CT.

Reprint requests to: Department of Neurology, University of Connecticut School of Medicine, 263 Farmington Ave., Farmington, CT 06032 (Dr. El-Mallakh).

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relatively more (5/333 and 5/308 respectively). Two of the three reported handicapped residents were in programs that had handicapped faculty members. Several obviously severe handicaps were included (Table 1)—e.g., blindness and paraplegia—but otherwise there was no gauge as to the severity. One emotional handicap is included (depression) (Table 1).

Table 1
A SUMMARY OF THE RESULTS OF THE SURVEY

Field	*Total Faculty*	*Total Residents*	*Handicapped Faculty*	*Handicapped Residents*
Neurology	141	106	1	0
Pathology	199	134	4	1
Psychiatry	141	167	3	2
Total	481	407	8	3

Type of Handicap:

Neurology—Cerebral palsy, 42-year-old male

Pathology— Paraplegia, 49-year-old male
Polio, deformed foot, 57-year-old male
Paralyzed vocal cords, 47-year old male
Partial nerve deafness, 39-year-old male
Depression, 26-year-old female*

Psychiatry— Hearing impaired, 60-year-old male
Hearing impaired, 63-year-old male
Blind, 48-year-old male
Blind, 32-year-old male*
Cerebral palsy, 29-year-old male*

*resident physician

Discussion

Nineteen hundred and eighty-one was the International Year of the Disabled (Figure 1). It was intended to be partly a celebration of the spirit of those who overcame tremendous obstacles, and partly a call for others to attempt to overcome their own handicaps. In the United States it is estimated that approximately 18,000 physicians are not in practice due to a physical disability.[5] Twenty-five percent of these physicians (i.e., 1% of all U.S. licensed physicians) have the potential of rehabilitation into active practice.[5] To achieve this goal, information on practicing physicians with handicaps is important but lacking.[5]

It was found that 1.24% of the physicians in this nonrandom sample had some form of physical or emotional disability. Of the three fields selected for the survey, neurology, pathology and psychiatry—the latter two requiring comparatively less physical activity than neurology—attracted the majority of the disabled physicians.

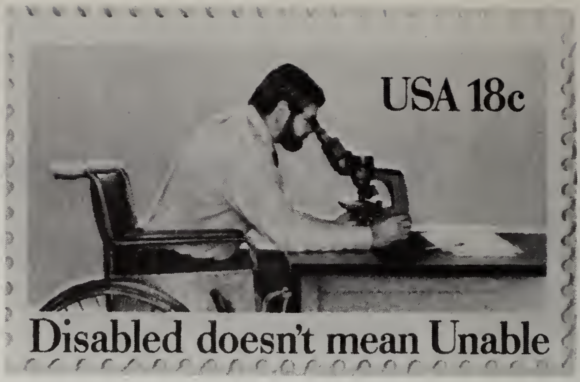

Figure 1
Stamp issued by the United States Post Office to commemorate the International Year of the Disabled, 1981, depicts a paraplegic looking through a microscope with the caption: "Disabled doesn't mean Unable."

Only two residents (0.5% of the sample) had a physical handicap. Both residents, a blind 32-year-old male and a 29-year-old male with cerebral palsy, were in the same psychiatry program which also included one blind and one hearing impaired faculty member. This indicates that residency programs which include disabled faculty members may attract or be more supportive of disabled residents. If this were generally true, it would imply that role models may play an important role for disabled medical students or young doctors. A larger sample would be needed to confirm this observation. Interestingly, there did not appear to be a clustering of handicapped faculty members within any one program.

It is believed that the design of this preliminary survey was by in large adequate. However, future larger surveys will include the following modifications: (1) the cover letter should be more specific as to the definition of handicap, and (2) the questionnaire should require some quantification of the severity of the handicap. (3) Further, to better improve the rate of response followup letters or phone calls to nonrespondents may be helpful.

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Medical Care of High School Athletes in Connecticut

JOHN E. CARTLAND, JR., M.D.

ABSTRACT—In February 1985 162 letters, with a questionnaire enclosed, were sent to the Directors of Athletics of all high schools in Connecticut. The purpose of the questionnaire was to learn what kind of medical care our student athletes were receiving. 66% return was received which was excellent. The survey reveals that every school needs and wants a full time trainer. The program initiated in the State of North Carolina in which faculty members take training to become certified trainers is suggested for serious study.

Introduction

In February 1985 162 letters with a questionnaire enclosed, were sent to the Directors of Athletics of the high schools in Connecticut. The purpose of the questionnaire was to learn what kind of medical care our student athletes were receiving, to see where its strengths and weaknesses were, and to suggest a way of improving that medical care. Some of the schools returned the questionnaire unanswered because they did not offer football. Since injuries can occur *not* only in football but also in gymnastics and cheerleading, in retrospect the questionnaire should have been all inclusive for both male and female participants. However, out of 150 questionnaires concerning football, about 100 were returned. This is a 66% return which is excellent and indicates considerable interest in the medical care of our student athletes.

Method

The team physician and trainer information questionnaire was adapted from the one devised by C.D. Rovere, M.D., and Associates.[1] Dr. Rovere is a Professor of Orthopedic Surgery and Director of Sports Medicine Unit at Bowman-Gray School of Medicine at Wake Forest University in Winston-Salem, North Carolina. The questionnaire was published in the November issue of *The Physician and Sports Medicine.* It is designed to solicit in depth information about the involvement of physicians and trainers in the health care of students who participate in athletics.

Results

The questionnaire did reveal very definite strengths and weaknesses in the student's medical care. The returns were quite equally divided between the large and small schools. Also the distribution of the returns from areas in the state were uniform.

The only question receiving 100% yes answers was the one pertaining to the availability of an ambulance. Every school had an ambulance either at the site of the contest or readily available by Walkie-Talkie.

Approximately 30% of the schools have an official school physician. Some of the time the school physician was the team physician, some of the time not. Several schools had various volunteers to cover home games. Some schools hired interns or residents from local hospitals to cover their home games. One school has a Pediatric Nurse practitioner. Several had an excellent relationship with local physicians who were very interested in their teams. One school has a father as the team physician, and the trainer is *his son.* This sounds like an ideal relationship.

80% of the schools have a physician to cover their home games. Most high school leagues have a rule requiring a physician to be in attendance dance at all home games. This may explain why less than 20% have their own physicians at away games because the home team will provide medical care. It is expensive as well as difficult to obtain a physician to go to away games.

Pre-season physical examinations are a necessary prerequisite for participation in all forms of athletics. The primary examination, ideally, should be done by the team physician, and, besides the physical exam, it should include a comprehensive past history of injuries and illnesses.[2] The survey reveals 55% of the physicals were done by the team physician while 45% were done by the student's own physician, or a designated school or team physician. Some were done by physicians who were hired just to do team physical examinations.

JOHN E. CARTLAND, JR., M.D., School Physician, Consolidated School District of New Britain, New Britain, CT.

The team physician supervised rehabilitation about 33% of the time. The orthopedic surgeon or the family physician were involved the rest of the time. The question involving when an athlete could return to competition revealed there was some cooperation between the team physician, the family physician, and occasionally the trainer.

The most glaring weakness revealed by the survey was the lack of a full time trainer at most schools. Only 25% of the schools had trainers available for both home and away games. Many of the respondents were very emphatic about desiring a trainer who would be available on a full time basis. In fact, several stated that they would like to have a *state law* making it mandatory for each and every school to have a trainer.

Discussion

The prompt and high percentage (66%) of returns of the questionnaire indicates marked interest in the medical care of athletes. Many comments were added to the questionnaire which varied from the ideal situation of having a physician and trainer at every Varsity, Junior Varsity, and Freshman games, both home and away, to many more who wanted a full time trainer. It is unrealistic to expect every school to have a physician present at every practice session as well as every game. However, every school should seek out a physician who wants to be the team physician as this will insure a physician who is truly interested in the players. The team physician should be available for pre-season physical examinations, and all home games of Varsity, Junior Varsity, and Freshman teams. He should be willing to attend 2-3 practice sessions a week, especially those involving bodily contact. When he is not at practice sessions, he should be readily available for any and all emergencies that may occur. The team physician should be the one to determine when a player may return to active status.

The survey reveals that every school wants and needs a full time trainer. With every School Board of Education stretching budgets to provide better education for their students, the availability of funds for a full time trainer is a problem. A program being developed in North Carolina may well provide the answer.[3]

The State of North Carolina is developing a program to provide full time trainers. They are suggesting that a member of the school faculty become a certified trainer. He or she would be available after school to care for the student athletes and would be in attendance at all games, home and away. Such a trainer would be able to establish a good rapport with the students and the team physician because he was full time. The trainer would receive extra compensation as the coaches and equipment managers do now. This approach would add the least strain to a school budget and would solve the problems for towns who can not afford a full time trainer, the ideal situation. The schools must provide better care and protection for their student athletes, both males and females. It is recommended that the trainer should not be a member of the Physical Education Department. Coaches should not have the added responsibility of being a trainer. Trainers are a necessity because better preventative care means less injuries.

Conclusion

Guidelines for Program Development in Sports Medicine were published in August 1981. These were developed by members of the Sports Medicine Committee which was convened by the Connecticut Advisory School Health Council and consisted of representatives from both the medical and educational communities.[4] In their Guidelines they reported on a recent survey of twenty-one high schools in the Greater Hartford area. The two recommendations for improving health care were the provision of athletic trainers and the establishment of standard guidelines for sport medicine programs. Excellent guidelines have been written, but as the survey reveals, there are too few trainers. The more affluent cities seemed to provide better care which is understandable. Better care should mean fewer injuries. Full time trainers working with coaches and team physicians would add greatly to improving medical care for athletes.

The program initiated in the State of North Carolina in which faculty members take training to become certified trainers should be seriously studied and seriously considered here in Connecticut. The interest in athletics and the additional compensation should be an added inducement for many faculty members. This program strains overtaxed budgets the least. Now is the time to start it.

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Important Advances in Clinical Medicine

Epitomes of Progress—Psychiatry

The Scientific Board of the California Medical Association presents the following inventory of items of progress in psychiatry. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in psychiatry that have recently achieved a substantial degree of authoritative acceptance, whether in their own field or special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Psychiatry of the California Medical Association and the summaries were prepared under its direction.

Light, Season and Affective Disorders

Animals living within temperate zones deal with dramatic changes in the amount of light they receive during different seasons. One of the most obvious physiologic manifestations of seasonality is the phenomenon of seasonal breeding. It is now well established that the pineal gland hormone, melatonin, mediates the antireproductive effects of decreased light exposure during winter months. Annual rhythms in humans have also been established, including, for example, seasonal variations in suicides, general mortality, a need for electro-convulsive therapy and the incidence of episodes of depression and mania.

Recently, a group of patients suffering from "seasonal affective disorder" has been described. These 29 patients had a generally "retarded" type of depression, beginning in late fall or early winter with increased sleep, appetite and carbohydrate craving. They often would "fly south" for winter vacations, at which time they would note spontaneous remissions of their depression. They often had episodes of hypomania during spring and summer. Speculating that the decreased duration of light in the winter somehow had triggered the depressive episodes (comparable, perhaps, to a human form of hibernation), the investigators treated 11 of these patients by extending their photoperiod to a more "springlike" condition for two weeks. Light was full spectrum and 10 to 20 times brighter than normal room light, but 1/40th as bright as bright daylight. It was deemed "biologically active" by virtue of its ability to suppress pineal melatonin production. Preliminary data indicated a significant antidepressant response in all patients, which, however, was often followed by a relapse within several days after light treatment was stopped.

Treatment of depression with light must remain experimental until well designed, positive replication studies are done. Further work then might show what demographic, clinical and circadian rhythm characteristics would most likely predict responsiveness to light therapy, and, particularly, how to use this new technique most effectively.

Rick J. Strassman, M.D.
Albuquerque

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Attention-Deficit Disorder in Children—Diagnosis and Treatment

The attention-deficit disorder with hyperactivity (ADDH) syndrome is one of the most common psychiatric problems in childhood. A diagnosis is most effectively attained by using systematic interviews with parents and

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children (such as the Diagnostic Interview for Children and Adolescents—a structured psychiatric interview), combined with rating scales completed by parents and teachers (such as the Conners).

The earliest view of the natural history of this syndrome was that children "outgrew" their problems by adolescence. An extension of this view is that treatment with stimulant medication should stop at the time of puberty because it would have a "stimulating" rather than a "calming" effect. Current research indicates that both of these views are wrong.

Prospective, retrospective and catch-up prospective studies of cases of the ADDH syndrome reveal the following. About half of the children are functioning relatively well in adolescence and adult life. The remainder have continuing symptoms and qualify for a diagnosis of ADDH residual state. In addition, a substantial number of children with the disorder have significant problems as adolescents, with educational retardation and antisocial behavior, including substance abuse. Serious antisocial behavior is present in 10% to 50% of different samples of children with the ADDH syndrome when they reach adolescence. Almost all of these children who have significant substance abuse manifest other forms of antisocial behavior, and almost all of those children with the syndrome who show antisocial behavior in adolescence have ADDH residual state.

These findings are also true of adult samples. In addition, several studies have found high rates of "dysphoric disorders" in adults with the ADDH syndrome.

Psychopharmacologic studies of both adolescents and adults with ADDH indicate that stimulant medication is still effective and does not produce a "stimulating effect. Sustained attention, impulsivity and motor activity are symptoms most affected by stimulants. Results of relatively long-term multimodality treatment studies suggest that multimodality intervention is quite effective in childhood. However, there is little evidence from published studies that treatment *limited to* childhood has any long-term effect in adolescence or adulthood.

Dennis P. Cantwell, M.D.
Los Angeles

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Hormones and Behavior

It is now well established that behavior influences hormone secretion, and, conversely, that altered circulating hormone concentrations can influence behavior.

Altered secretion patterns of many of these hormones have been identified in cases of acute and chronic stress, in psychiatric illnesses including mania, depression and schizophrenia and as a result of drugs that act on the central nervous system—such as neuroleptics, alcohol and opiates. Perhaps most relevant to clinical psychiatry is the use of these hormone changes as tests to aid in the differential diagnosis of certain illnesses and to follow response to treatment. The dexamethasone-suppression test (DST) is the best known of these, having been proposed as a laboratory aid in the diagnosis of endogenous or melancholic depression, the subtype of major depression often requiring somatic treatment (antidepressants, electroconvulsive therapy). In the DST, the synthetic glucocorticoid dexamethasone, usually 1 mg, is given orally about midnight and the serum cortisol concentration is measured at certain times the next day. Dexamethasone normally suppresses adrenocorticotropic hormone and cortisol secretion for a full 24 hours, whereas 30% to 60% of patients with endogenous depression show an early cortisol escape, most likely on the basis of increased hypothalamic driving of the anterior pituitary-adrenal cortex. The practical application of the DST as a diagnostic aid has been hampered by issues of varying sensitivity (percentage of index cases with abnormal—that is, true-positive—DST results) and specificity (percentage of comparison cases with normal—that is, true-negative—DST results) and interference in the test results by a number of drugs and medical conditions. At present, the DST appears to be most useful in following the adequacy of treatment. Those patients with an abnormal pretreatment DST response who improve symtomatically with treatment but continue to have an abnormal test result are at greater risk for relapse than those patients whose DST findings revert to normal. The former patients may require electroconvulsive therapy in addition to pharmacotherapy for a full remission. In some patients with recurrent depression, the DST findings may again become abnormal several weeks before a clinically evident relapse. This is a promising aspect of the test that requires further study.

Similar limitations apply to another widely used neuroendocrine test for endogenous depression, the thyrotropin-releasing hormone (TRH) stimulation test, in which TRH is given intravenously and the serum thyrotropin (thyroid-stimulating hormone) level is measured. A thyrotropin response below a certain criterion level is considered blunted and thus abnormal. At best, both the DST and the TRH test should be applied only in selected cases and with full cognizance of their limitations both generally and in specific patients. They are neither screening tests nor substitutes for a careful clinical assessment.

Triiodothyronine, or T_3, the metabolically active thyroid hormone, may be a useful therapeutic adjunct to tricyclic antidepressants in some endogenously depressed patients who are refractory to the latter medications alone, even though such patients do not have clinically evident hypothyroidism. Presumably, the T_3 sensitizes postsynaptic neurotransmitter receptors in the central nervous system, similar to the mechanism proposed for the adjunctive effect of lithium in persons with tricyclic-resistant depression.

Robert T. Rubin, M.D., Ph.D.
Torrance, California

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Positron Emission Tomography in Psychiatric Disorders

Positron Emission Tomography (PET) is a new computerized tomographic technique that allows the visualization of brain structures relative to their uptake of radioactive tracers. Tracer substances are manufactured that contain unstable atoms which decay to emit a positron. This positron in turn annihilates with an electron to produce gamma particles. This radiation is picked up by sensors and a computer program is used to reconstruct a picture based not on X-ray density but on the local concentration of the tracer. PET scans thus permit us to examine the biochemical functions of the brain in which the various positron-labeled tracer substances are involved.

The PET scan presently is strictly a research tool, though it may have applications in clinical psychiatry in the future. To date most studies have involved substances like water ^{15}O to look at blood flow or fluorodeoxyglucose ^{18}F to look at glucose metabolism. A few studies have been done using labeled drugs, most notably spiroperidol, which binds to and thus allows localization of dopamine receptors.

PET studies of glucose metabolism are already yielding interesting findings in cases of major psychiatric illness. In patients with chronic schizophrenia, glucose metabolism in the frontal lobes appears low when compared with that of posterior brain regions. This pattern is the reverse of that seen in normal persons. In mood disorders one group reports that patients with bipolar (manic-depressive) depression have low metabolic rates in all supratentorial brain structures when compared with normal persons, patients with bipolar depression who are in a manic state and even those with unipolar depression. In contrast, patients with unipolar depression show a decrease in the metabolic rate of the caudate nucleus relative to that of the person's brain as a whole. In another study, using water ^{15}O to study blood flow, those patients with panic disorder in whom an infusion of sodium lactate causes a panic attack were shown to have a decrease in blood flow to the left hippocampal gyrus compared with that on the right. These two interesting studies await replication.

Lewis R. Baxter, Jr., M.D.
Los Angeles

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Use of Carbamazepine in Mood Disorders

Carbamazepine (Tegretola) is used extensively to treat partial complex (psychomotor or temporal lobe) and major motor (grand mal) seizures. In the past few years, carbamazepine has been shown to have value in treating cases of bipolar (manic-depressive) disorders. In studies carried out first in Japan and then in this country this drug has been remarkably effective both in treating patients with manic episodes and for maintenance to prevent recurrences. Its efficacy is on a par with that of lithium carbonate and many patients who do not respond to or cannot tolerate lithium can be effectively treated with carbamazapine. At present, it is usually only used in such patients. Carbamazepine may be effective in treating patients with depression, both bipolar and unipolar, though this is less well documented than its effects in cases of mania.

Treatment begins with 100 or 200 mg given twice a day, which increases, as patient tolerance permits, to a total of 600 to 1,600 mg a day (average dose about 1,000 mg a day). Carbamazepine blood concentrations do not correlate with therapeutic response in bipolar illness. Carbamazepine is compatible with most other psychiatric drugs. Some patients have required treatment with both carbamazepine and lithium to get an adequate response, though there are reports of occasional central neurotoxicity.

Carbamazepine is closely related to the tricyclic antidepressants and should not be added to the regimen of a patient already taking a monoamine-oxidase inhibitor. As with other tricyclics, monoamine-oxidase inhibitors can be added once a person is taking carbamazepine.

Many physicians have been unduly frightened about carbamazepine because of early reports of aplastic anemia occurring. Most of these cases were in elderly patients with numerous medical problems being treated with many drugs. Despite the increasing use of carbamazepine by neurologists and psychiatrists, there has not been a corresponding increase in cases of aplastic anemia related to its use. Side effects with the use of carbamazepine consist of those that can be seen with tricyclic antidepressants, but, in addition, there seems to be an increased incidence of dizziness (often true vertigo), pruritic rash and a mild lowering of the leukocyte count. Liver toxicity rarely occurs.

Lewis R. Baxter, Jr., M.D.
Los Angeles

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Update on Electroconvulsive Therapy

Electroconvulsive therapy remains a viable and important treatment in psychiatry. In California, for example, some 2,600 patients receive it each year (in spite of the strict legal requirements in the state).

More than a dozen different antidepressants are available in the United States, yet many patients with major depression respond only to electroconvulsive treatment. Response rates in the order of 70% to 90% have been shown. In some cases of severe life-threatening depression or in patients who are severely ill medically, electroconvulsive therapy is the treatment of choice. Manic patients who are not responsive to conventional treatments have about a 90% response rate to this treatment. Although manic exhaustion and depressive inanition were once common causes of death, today they are quite rare. Schizophrenic patients in acute stages who are unresponsive to standard treatments or who have experienced severe side effects, such as agranulocytosis or severe tardive dyskinesia, have a 75% response rate with electroconvulsive therapy. It is extremely safe, with a mortality rate of only 0.2 deaths per 10,000 treatments in California from 1977 to 1983.

There are virtually no absolute medical contraindications to electroconvulsive therapy. Although a brain tumor or a recent myocardial infarction are generally considered contraindications, it has been successfully given to patients with such a condition when absolutely essential for the patient. The most common side effects are (muscle contraction) headache and transient memory difficulty.

With premedication, anesthesia and hyperoxygenation, patients feel nothing and are often surprised, on awakening, to find that the treatment is completed.

New equipment using brief pulse stimuli allows a patient to receive less electrical energy than from a standard sine wave apparatus. Unilateral electrode placement is an option available to further lessen the transient memory disturbance that follows electroconvulsive therapy. However, not all patients who respond to this treatment will respond to unilateral treatment. The presence of a cerebral (not peripheral) seizure is necessary for a therapeutic response. Seizures can now effectively be monitored using electroencephalography to ensure that a therapeutic treatment is given. The expanded use of multiple monitored electroconvulsive therapy is being explored. This involves inducing three to five seizures in one treatment session in an attempt to effect a more rapid therapeutic response with fewer anesthesia inductions.

Barry Alan Kramer, M.D.
Los Angeles

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The Behavioral Treatment of Obesity

Obesity is a major health problem in the United States. Public health statistics indicate that approximately 11 million men in the United States (19%) are obese; 18 million women (28%) are obese. For both men and women, the percentage increases with age. The mortality and morbidity of every disease are increased by the concurrent presence of obesity. Lowered self-esteem and a lifelong pattern of fighting negative cultural stereotypes are prevalent in obese persons.

Many studies have shown that obesity can be treated by modifying the antecedents to eating behaviors—that is, by changing responses to overt and covert stimuli, patters of self-instruction and attributions to internal food cues and by decreasing cue salience. Eating behaviors can be changed through contingency contracting, social reinforcement, group approval and self-reward. Patients can be taught to change their eating habits by dietary and behavioral instructions—for example, by eating more slowly, eating in one place and emulating the food choices and eating style of their thin friends. Although not an eating behavior, exercise or an increase in physical activity is important in any weight-loss or weight-maintenance program.

Widespread replications have shown these techniques to be effective. Patients lose about ½ kg (1 lb) per week in behavior-modification programs for obesity. Stunkard showed that initially this effect can be enhanced by the use of appetite-suppressing medication; however, patients who received only behavior-modification instruction have significantly better weight-loss maintenance than their matched peers in traditional counseling or drug-assisted therapies.

For patients who are as much as 40% overweight, current clinical practice is a dietary prescription of 750 to 1,200 calories with behavior-modification techniques for losing weight and maintaining weight loss. For those with more weight to lose, more aggressive therapies are necessary. For moderately obese patients—40% to 100% overweight—a protein-sparing modified fast of 320 to 400 kcal followed by a behavioral treatment program for maintaining weight loss is probably most effective. For the morbidly obese—patients 100% or more overweight who are resistant to dietary counseling or fasting program—the vertical banded gastroplasty operation is the treatment of choice.

James M. Ferguson, M.D.
La Jolla, California

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The Role of Transference in the Doctor-Patient Relationship

In its traditional usage, the concept of transference has described our tendency to bring perceptions and expectations to our current interpersonal interactions that derive from earlier experiences with significant figures in our lives, rather than to relate specifically on the basis of the realistic attributes and behaviors of the person with whom we are interacting. Originally devised specifically to help us understand otherwise puzzling aspects of the relationship of a patient to the therapist in the psychoanalytic therapeutic situation, the concept was soon broadened to include perceptions and expectations brought to all relationships with significant figures in our lives (the transferences of everyday life) and, of course, within that, to the perceptions and expectations brought by patients to their physicians, as healers, as authorities and as persons to whom we entrust our care and who can do us good or harm (all aspects of the doctor-patient relationhsip).

Recent developments in psychodynamic understanding have made more explicit what is now called (by Gill) the two-way (social) rather than the one-way (asocial) paradigm of the transference. The one-way (asocial) paradigm is the traditional view just outlined, that transferences represent distortions of the realities of the current interactions by perceptions and expectations that derive from the past and are imposed upon and thereby color our perceptions of the new relationship in the present. According to this concept, a patient imposes his or her often inappropriate perceptions and expectations derived from past experiences upon the neutral, objective physician. The therapist as the more objective party and better judge of what is realistic and appropriate can then help the patient to differentiate perceptions that are distorted from those that are realistic.

According to the two-way (social) paradigm, the transference is constructed out of the interaction of two people, each of whom tries to plausibly construe his or her experience of the other in the relationshsip. This construing of the relationship depends on the actual behaviors, attitudes and interactions as they are perceived through the expectations that one brings from past experiences with similar people or similar situations. In this concept, both parties try to make plausible sense of their relationship, both influence the way the other perceives them and both are influenced by the other's actual behaviors and by expectations that derive from their own personal pasts. In this conception it is not immediately clear what is realistic and what is distorted and how much a patient's way of construing the relationship makes sense in terms of how the therapist's actual attitudes and behavior are remindful of or confirm perceptions and expectations that were originally grounded in the patient's earlier life experiences.

The newer conception of the transference entails in turn an altered handling of it. Rather than seeing transference manifestations, with their roots in past experiences, only in terms of their inappropriateness to the present relationship and therefore as unrealistic, a physician might now look first to the current interaction with a patient to see what in it might be plausibly construed by the patient as if it were the same as, or a repetition of, an earlier relationship pattern. This becomes then an additional avenue to understanding and to tactful handling and tactful behavioral alteration by a physician in interacting with patients.

Robert S. Wallerstein, M.D.
San Francisco

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Indications for Monitoring Psychotherapeutic Drug Concentrations

The measurement of concentrations of psychotherapeutic drugs in serum has recently been introduced into the field of psychiatry. The clinical indications for these drug level measurements are still being developed but the following generalizations can be sifted out of the literature.

Lithium Ion

Lithium ion is readily determined in serum. The recommended therapeutic range of 0.8 to 1.4 mmol per liter may be valid only for cases of acute mania; maintenance levels of 0.4 mmol per liter may be sufficient. Optimal maintenance levels and schedules are subjects of much current investigation.

Tricyclic Antidepressants

Suggested optimal tricyclic antidepressant concentrations are 100 to 300 ng per ml (400 to 1,100 nmol per liter) for desipramine hydrochloride, 50 to 150 ng per ml (200 to 550 nmol per liter) for nortriptyline hydrochloride and 100 to 200 ng per ml (400 to 750 nmol per liter) for protriptyline hydrochloride. Some investigators have noted deterioration at concentrations greater than 150 ng per ml of nortriptyline. For the tertiary amines, the following tentative ranges have been proposed: imipramine hydrochloride plus desipramine, 150 to 300 ng per ml; amitriptyline hydrochloride plus nortriptyline, 150 to 300 ng per ml (nortriptyline and desipramine are formed metabolically from amitriptyline and imipramine, respectively).

The utility of measuring such concentrations is controversial but appears to be most useful in cases of poor treatment response. The drug concentrations can then be used to assess whether poor compliance (which may exceed 50%) or aberrant metabolism is present. The use of drug concentrations is advocated to avoid toxic effects in high-risk populations, such as cardiac patients or elderly persons. Beyond these indications, the use of blood concentrations of tricyclic antidepressants is not considered cost effective by most authors.

Neuroleptics

Neuroleptic drug monitoring is in its infancy. Haloperidol is the best studied drug. Available studies suggest that both excessively high or low levels of haloperidol are associated with a poor clinical outcome. Studies are in progress with thiothixene and fluphenazine hydrochloride. At present no indications for measuring antipsychotic drug activity have been developed.

Benzodiazepines

Although benzodiazepines can be readily assayed, there is little agreement on the interpretation of serum concentrations. A major problem is the heterogeneity of conditions treatable with these agents.

Joseph R. Magliozzi, M.D.
Sacramento, California

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Mass Hysteria

Recorded in the medical literature for centuries, mass hysteria continues to perplex both clinician and researcher. Although recent studies have clarified the characteristic patterns of such epidemics, sudden outbreaks of illness routinely stir up controversy about whether they are physical or psychological in origin. With public alarm about environmental pollution increasing during the past decade, attempts to find toxic causes for these epidemics have intensified.

An estimated four to six separate outbreaks of hysteria reach public attention each year, but the actual incidence is unknown. Mass hysteria is defined as the occurrence in a group of people of a constellation of physical symptoms suggesting an organic illness but resulting from a psychological cause, with the typical epidemic affecting from 30 to several hundred people. The characteristic features of mass hysteria that help differentiate such epidemics from those due to physical causes include the absence of laboratory results and physical findings confirming a specific organic cause; a preponderance of the illness in girls or women; the apparent transmission of illness by sight or sound, or both; the presence of hyperventilation or syncope; a preponderance of illness in adolescents or preadolescents; benign morbidity, often with rapid spread followed by rapid remission of symptoms; relapses of illness in the setting of the original outbreak; and evidence of unusual physical or psychological stress.

The usual question is how far to pursue various chemical tests without undertaking an endless search for an organic cause. No single toxicologic or epidemiologic finding is pathognomonic; sudden outbreaks of illness are sometimes found to have organic psychological causes, and both possibilities should be explored initially. Intervention should also include dispersion of the group and discontinuation of extensive environmental and laboratory investigations once the characteristic pattern of hysteria emerges.

Gary W. Small, M.D.
Los Angeles

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PROFESSIONAL LIABILITY PREMIUMS have increased by 44.8% in the last two years, the AMA Task Force on Professional Liability and Insurance said in its response to the Assn. of Trial Lawyers of America. Even in low-risk specialties, premium increases have been dramatic. General practitioners and physicians practicing internal medicine have experienced premium increases of 31.4% and 32.4%, respectively, since 1982. Citing the latest information from the AMA Center for Health Policy Research, the task force said that premium costs for many highly specialized physicians now approach one-third of their gross incomes, driving some physicians out of practice and causing others to provide fewer high-risk services. The level of premiums varies greatly particularly across specialties and locations. Premiums are substantially higher for surgical specialties and obstetrics/gynecology. In 1984, the average obstetrician/gynecologist paid $18,800—more than 16% of before-tax net income—on insurance premiums alone. In some states, the premiums are much higher. For all physicians across the country, 1984 premiums averaged $8,400 or almost 8% of before-tax net income.

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A Primer on EMS for Connecticut Physicians

JONATHAN BORAK, M.D.

The development of community based systems capable of providing sophisticated emergency medical services (EMS) outside of hospitals has taken place in less than two decades. As recently as 1966, nearly 50 percent of the nation's ambulance services were provided by morticians; equipment standards were rarely promulgated and close to 50 differing instructional programs were being used to train ambulance attendants.[1] Publication of such findings by the National Academy of Sciences/National Research Council prompted Congress to establish nationwide standards for emergency medical services (Highway Safety Act of 1966)[2] and ambulance design (National Traffic and Motor Safety Act of 1966).[3] The former legislation required the states to develop highway safety programs according to standards formulated by the Secretary of Transportation. These acts, and their state equivalents, formed the first important base for modern EMS systems.

Three years later, the first national conference on EMS led to the development of standardized training programs and certification processes for Emergency Medical Technicians (EMTs) along with a national EMT registry, proposed methods for organizing community EMS councils and suggested criteria for categorizing hospital emergency capabilities. Formal systems planning was introduced in 1973 with passage of the Emergency Services System Act[4] which provided federal money to support the development of comprehensive, regional EMS programs. To be eligible for funding, EMS systems were expected to specifically consider manpower and training needs, communication and transportation capabilities, adequacy of regional hospital services, integration of community disaster plans and public safety organizations, standardization of patient record keeping, consumer involvement and education and also independent review and evaluation. From this Act, and its mandated concerns, has evolved contemporary EMS.

In spite of the systematic structure of EMS and its reliance upon public planning and input from both health professionals and consumers, the actual organizational and operational methods of EMS remain often obscure. Even within the medical community, EMS policies and procedures are generally not well understood. Confusion and conflicts between EMS personnel and other health care providers occur with unfortunate frequency. The following description of EMS in Connecticut may help to clarify some common misunderstandings and promote smoother integration of EMS into our state's health care network.

Governance

The Department of Health Services is the state agency responsible for the planning, coordination and administration of a statewide emergency medical care service system. The Commissioner is required to develop annually a statewide plan for the coordinated delivery of EMS, carry out an annual inventory of EMS resources, establish minimum standards for communication, transportation and training capabilities, categorize hospital emergency departments and determine ambulance rates. Generally, these functions are carried out by the Department's Office of Emergency Medical Services (OEMS).

Day-to-day operations are governed at the regional level. There are five EMS regions in the state corresponding to the state's five Health Service Agency (HSA) regions. Each region must establish an EMS Council comprised of representatives from local government, public safety services, medical and nursing professions, ambulance service providers, educational institutions, planning agencies and consumers. Health professionals represent only a small minority of its members. Along with an annual inventory of regional EMS resources, the Councils are responsible for developing annual regional EMS plans that evaluate needs, assure adequacy of trained personnel, provide continuous training programs and assure

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JONATHAN BORAK, M.D., Director of Emergency Services, Hospital of St. Raphael; Assistant Clinical Professor of Internal Medicine, Yale University School of Medicine; Chairman, Committee on EMS Connecticut State Medical Society.

Reprint requests to: Hospital of St. Raphael, 1450 Chapel Street, New Haven, CT 06511 (Dr. Borak).

categorization of hospital emergency capabilities. These plans must be responsive to needs identified by the regional HSA.

To accomplish its duties, the Councils are required to appoint a regional EMS Coordinator who provides staff to the Council, facilitates the development of inventory and EMS plans, monitors regional EMS activities and acts as liason to the Director of OEMS. The skills required of a Coordinator are mostly administrative and political; knowledge of EMS activities is essential but a background in health care is not.

Decisions concerning medical care, such as the development of treatment protocols, the determination of advanced level training needs and the assessment of skills adequacy among advanced level EMTs, are made by regional Medical Advisory Councils (MAC) which are standing committees of the Councils. Membership is usually restricted to the directors of regional hospital emergency departments as well as one or more physicians involved in EMS and an attorney. The recommendations of the MACs are almost always accepted by the Councils and thus promulgated as regional policy.

System Components

Ambulance Services and *Rescue Squads* are overseen by OEMS. Commercial services must be licensed while volunteer and municipal services require certification. To obtain certification or licensure, a service must show that it complies with technical standards including vehicle design and equipment as well as documenting sufficient working capital and insurance coverage. In order to obtain a license or certificate for a new or expanded service, it is also necessary for the proposed provider to demonstrate that such services are needed, a process that requires consultation with the regional Councils.

Emergency medical service providers are categorized by capability and licensed or certified accordingly. At the current time, four distinct levels of service are recognized; a fifth level will be recognized once proposed regulations are enacted. First Responders, or R1 services, are generally public safety services such as local or state police. They must provide at least one certified medical response technician (MRT), maintain two-way radio communication with the regional EMS system and be able to perform CPR, advanced first aid, triage and accident scene management. First responders do not transport patients. Communities need not designate an R1 service, but it is recommended where response times for more advanced services exceed ten minutes.

Basic level providers, or R2 services, are typical ambulance or rescue squads and represent the majority of EMS providers. They must be staffed by at least basic level EMTs (EMT-A). Along with R1 skills, they must be able to assess victims of medical emergencies, evaluate vital signs, immobilize skeletal injuries, dress wounds and burns, deliver babies and transport patients.

Intermediate level providers, to be designated as R3 services, are capable of initiating intravenous therapy, employ advanced airways and military anti-shock trousers (MAST), and provide all R2 skills. They must be staffed by at least one intermediate EMT (EMT-I) and one EMT-A.

Advanced life support (ALS) providers, to be known as R4 services, are staffed by at least one advanced level EMT (EMT-Critical Care Technician or EMT-CCT) and one EMT-A. In addition to R3 skills, they administer selected medications, defibrillate and transmit EKGs by telemetry. Paramedic providers, or R5 services, are staffed by at least one paramedic (EMT-P) and one EMT-A. The distinction between R4 and R5 providers will rest primarily on the actual training undertaken by the advanced EMT, paramedics having received more extensive backgrounds that EMT-CCTs and being therefore skilled in more advanced techniques.

Emergency Medical Technicians comprise the largest number of EMS personnel and provide the greatest share of EMS care outside of hospitals. Basic level EMTs (EMT-A) must be at least 18 years old and successfully complete a standardized 100-hour course. Topics covered include CPR, advanced first aid, recognition of medical emergencies, elementary concepts in physiology, and limited physical examination skills. EMT-As do not administer medications or IVs and they do not use defibrillators. EMT-A courses are given frequently throughout the regions. Courses must be directed by an OEMS certified EMS Instructor (EMS-I) who is an EMT, has successfully completed a state approved Instructor's course and has been recommended to OEMS by the regional council. Recertification examinations must be passed every two years. There are nearly 435,000 EMT-As nationally and 8000 in Connecticut. Nearly 60 percent work as volunteers.

Intermediate level EMTs (EMT-I) must be experienced EMT-As who have successfully completed an additional course of about 40 to 100 hours. Topics taught in greater depth include cardiovascular physiology and shock, respiratory management with esophageal obturator airways, trauma management and use of IV fluids. Like EMT-As, they do not employ drugs or defibrillation. Courses are coordinated by the regional Councils and EMT-Is are required to participate in regular continuing education programs. They are recertified by annual examinations. EMT-Is were originally intended for rural areas, where long transportation times to hospitals contributed to treatment delays and deaths from trauma and shock. Their current use in urban and suburban areas is less easily justified. About 23,000 EMT-Is operate around the country and 1000 in Connecticut.

Paramedics (EMT-P) and advanced life support EMTs (EMT-CCT) are experienced EMT-As who have successfully completed an approved course often lasting 500 to 1000 hours. Standard paramedic instruction is patterned after a 15-module course developed by the Department of Transportation which divides training between didactic and practical sessions. Along with advanced concepts in physiology and behavioral medicine, course-topics include pharmacology and medication administration, use of endotracheal intubation, cardiac monitoring and defibrillation. These are the individuals who staff mobile intensive care units. Certification of EMT-Ps in Connecticut requires adequate performance on a nationally administered Paramedic written examination, practical skills testing and supervised work in the EMS system. Additionally, EMT-Ps and EMT-Is must be approved by the individual Councils for each region in which they work. Recertification testing is required annually and regular participation in continuing education programs in mandatory. There are nearly 33,000 paramedics nationally and 300 in Connecticut. About 52 percent of the US population and 45 percent of Connecticut residents have access to paramedic or ALS services.

A central *Communication Center* capable of integrating all EMS communication functions is required in each region. Where possible, the center should be accessible by phone dialing 911. (By law, a "911 System" will be implemented statewide by 1989.) Among its responsibilities are to screen incoming emergency calls, dispatch appropriate providers, assure communication between field units and hospital emergency departments, monitor response times and maintain records of EMS activities.

Hospital Emergency Departments (EDs) are the recipients of nearly all patients entering the EMS system. The departmental directors are expected to be actively involved in EMS and professional staff must be knowledgeable of regional and state policies and protocols. The EDs provide most of the training staff for EMT-I and EMT-P courses and testing. They provide both on-line (real time) and off-line (delayed) supervision and evaluation of advanced EMT activities. As described below (Medical Control and Direction), ED physicians direct the actual field work of advanced EMTs via radio communication and are liable for many of their actions.

System Controls

The regional Councils are responsible for evaluating the EMS systems and the regional Coordinators are required to monitor regional EMS activities. Generally, this is accomplished by developing regional standards promulgated as operational policies and treatment protocols, assuring that these standards are taught to EMS personnel and then determing compliance. The power to police regulatory standards rests with the Commissioner, although the Councils can advise or assist in determining when standards have not been observed.

Statewide treatment protocols for both Basic and Advanced ambulance services have not yet been published, although preliminary drafts have been circulated to regional Councils and final publication is expected shortly. In their absence, a certain degree of heterogeneity between regions exists. Because regions are permitted to set higher standards than those mandated by the Commissioner and OEMS, such heterogeneity is likely to persist. To some extent, variability of protocols across regions results in controversy and confusion when patients are transported from one region to another. The development of a statewide helicopter rescue service, which by its nature is likely to regularly transport patients across regional boundaries, may catalyze the acceptance of uniform treatment protocols for all regions.

Monitoring of compliance with policies and protocols is often performed by Communication Centers and hospital ED staff. One effective and commonly employed system is to compare all ambulance treatment records, or Run Forms, with the corresponding ED medical record. This permits the ready recognition of unnecessary or inadequate pre-hospital treatments and allows a means of contrasting patient assessments made by EMTs and ED physicians. To reconcile disputes and to evaluate the appropriateness of radio communications between EMTs and EDs, recordings of all communications are maintained and may be reviewed by ED directors, ambulance service supervisors and officers of the regional Councils.

Medical Direction and Control

Medical Control is the entity accountable for the medical competence of an EMS system. In its broadest sense, Medical Control encompasses responsibilities ranging from providing training for physicians, nurses and EMTs to retrospective reviews of system performance. More narrowly and most importantly, Medical Control permits the medical treatment activities of EMS outside of hospitals by extending its license to practice to the physician extender EMTs and paramedics of the community. This latter function is termed Medical Direction in proposed regulations.

In most cases, Medical Control and Direction is provided by one or more hospitals of a region, usually by the medical staff of the hospital ED. Occasionally, outside of Connecticut, it is the responsibility of one or a group of physicians. In theoretically "best" systems, Medical Control is in a single hospital, called the Resource Hospital, which directs all EMT-I and EMT-P medical activities; regional hospitals which receive patients but do not exert Medical Control or Direction are known as Associate Hospitals. In other systems, the role of Resource Hospital is rotated among several regional hospitals. It is common throughout Connecticut for all EDs participating in regional EMS to entend Medical Direction within its own community and to ambulances transporting patients to that hospital.

To achieve Medical Control, it is necessary to assure that EMTs and paramedics follow protocols strictly and obtain all other necessary instructions and orders from an appropriate licensed physician. In nearly all cases, such a physician is available by radio communication to an ED providing Medical Direction. In some cases, Medical Direction may be provided by a non-EMS physician who extends his license to the physician extender EMTs and thereby assumes liability for their actions. As described below, this latter situation is frequently associated with confusion and conflict.

Medical Direction may be denied to an individual EMT or service which fails to comply with regional or hospital standards. The relationship between physician and physician extender is such that a hospital or its ED medical staff may refuse to extend Medical Direction when it is deemed to pose potential risks to patients. In such cases, state decertification may follow or be persued independently of a hospital's withdrawal of Medical Control.

Common Conflicts and Confusions

A limited number of regularly recurring conflicts and confusions often disrupt the interface between EMS and community health care providers. To some extent, these problems stem from misunderstandings about the ethical, legal and medical restrictions imposed upon physician extender EMTs and paramedics. Issues of conflict frequently involve EMTs accepting orders from non-EMS physicians, the role of Good Samaritan physicians in EMS operations, respect for DNR orders in nursing homes and transportation of deceased bodies.

EMTs and paramedics will accept orders from private physicians caring for patients entering the EMS system. Although they cannot be ordered to exceed their levels of training and skills, they can be directed to alter protocols or withhold specific interventions. Such deviations from protocol require the continued presence of the private physician who then exerts Medical Direction and is responsible for the EMTs' actions. In such cases, the private physician is expected to accompany the patient and EMTs to the destination hospital where the patient can be transferred to the ED medical staff. If the physician does not remain with the patient, then the EMTs are required to return to protocols and reestablish Medical Direction and Control with the appropriate hospital ED.

A private physician may effectively modify EMS protocols for specific patients by contacting the ED physician in the destination hospital and explaining the need for such deviations. This can be accomplished by telephone or via the EMTs' radio. Based upon that ED physician's judgment, protocol alterations can then be ordered by radio without disrupting normal Medical Control or requiring the physician to accompany the patient to the ED.

Good Samaritan physicians stopping at roadside accidents or cardiac arrest scenes often find difficulty in offering their help to EMTs. From the standpoint of paramedics, who repeatedly practice critical care protocols in order to save precious seconds, the well intentioned interruption by a Good Samaritan seems a disruption that delays patient treatment and transport to the ED. Moreover, the Samaritan is as likely to be a pathologist or psychiatrist as a trauma surgeon or cardiologist. However, a properly identified Good Samaritan physician may assume Medical Control at such times. He must agree to remain with the patient until arrival at the ED and he assumes responsibility for the patient's care. In these situations, it is helpful if that physician speaks directly by radio to the ED physician and confirms his involvement in the case.

As EMTs can only take orders from a physician who is present or from a Medical Direction ED, so they cannot follow written orders other than system protocols. Hence, EMTs and paramedics cannot respect written DNR orders. This issue arises often in nursing homes. In all cases where life is possible, EMTs are instructed to provide all possible care unless specifically ordered to do otherwise by a Medical Control physician.

From a system perspective, it is usually inappropriate to summon an EMS response to a dying DNR patient. Transportation of terminal DNR patients to hospital or hospice can be effected outside of the EMS system by requesting non-emergency transport by a local ambulance service. Generally, all calls to 911 Communication Centers are regarded as emergency calls. Ambulance services have separate phone lines for calls of a non-emergency nature.

EMS personnel are often called to persons who are obviously dead, although the transport of dead bodies is not an EMS function. To deal with these situations, the Commissioner of Health and the Chief Medical Examiner (CME) published Guidelines for "Transportation of Deceased Bodies" [5] which involve both EMS and private physicians. An EMT may determine that a person is "presumed to be dead" when death is obvious. In those cases, EMTs are instructed to use the following protocol:

1. If death appears to be of natural cause, notify attending physician.

2. If the attending will not respond to the scene, then the EMT must do the following:
   a. Notify attending physician of presumed death.
   b. Ask attending physician when patient was last seen by him and note in writing.
   c. Ask attending physician to notify funeral home of family's choosing and arrange a time to view the body there.
   d. If attending physician refuses to cooperate, notify the police and ask them to call the Office of the CME.

3. If there is no attending physician, notify the police and ask them to call the Office of the CME.

Following these protocols, EMTs help to arrange non-ambulance transport of dead bodies directly to funeral homes and ambulances and EMS personnel more quickly return to EMS functions. This also frees hospital EDs of the disagreeable task of receiving the community's several-days dead.

Conclusion

The basic structure and function of community EMS systems are straightforward and understandable to health care providers who choose to spend the little time necessary to learn about them. Nevertheless, confusions and conflicts do arise where EMS and other elements of the health care system interface. In part this is due to failures of EMS personnel to adequately explain their functions and protocols and in part to non-EMS providers who fail to communicate their concerns and questions about EMS. Physicians who encounter problems or wish to raise issues about EMS will generally find these best directed to the ED Directors of their local hospitals. If that avenue does not serve, the Committee on EMS of the Connecticut State Medical Society will try to provide appropriate responses.

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This statement has been endorsed by the Committee on Emergency Medical Services, of the Connecticut State Medical Society and the Connecticut Chapter of the American College of Emergency Physicians.

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FUTURE PARTICIPATION RATES in Medicare will depend to a large extent on federal marketing efforts for participating physicians and the impact of the fee freeze on non-participating physicians, the AMA Center for Health Policy Research said. The center reached its conclusion after a study of economic factors in physicians' decisions last year about whether to sign up for the Medicare participating physician program. In a sample of 476 non-federal patient care physicians, the center found that the physicians who were more likely to participate last year were those who had previously assigned a larger percentage of patients or whose usual fees were relatively close to the Medicare prevailing fee (a high ratio). The higher the past assignment rate, the more likely the physician was to participate. A 1% increase in past assignment rates increased the probability of participation by a little more than one-half percent. As expected, the more the physician's usual fee was covered by the prevailing charge, the more likely he was to participate. A 1% increase in the ratio of the Medicare prevailing fee to the physician's usual fee increased the probability of participating by one-tenth of one percent. Overall, the likelihood that any physician would participate last year was a little more than one-third, with urban and non-board-certified physicians nearly twice as likely to participate as their rural or board-certified colleagues. The more heavily urbanized northeast and north central regions of the United States had larger participation rates than the more rural south and west. Internists, psychiatrists, anesthesiologists, radiologists, and pathologists had the highest participation rates. Surprisingly, one-fifth of those physicians who assigned no patients in the past decided to participate, and nearly one-fourth of those who previously had assigned all patients decided not to participate.

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The Effect of Prospective Reimbursement on Trauma Patients

LENWORTH M. JACOBS, M.D., M.PH., F.A.C.S.

The changing climate of prospective reimbursement has already affected the manner in which hospitals and physicians think about the practice of medicine. This climate is bringing new conceptual approaches to setting standards for emergency health care and the manner in which such care is compensated.

Historical Background

Health-services planning became an issue of public concern in World War II when the U.S. Senate inquired into the adequacy of the nation's health because many military inductees were found to be unhealthy. The Surgeon General of the U.S. Public Health Service proposed establishing planning agencies throughout the country to guide the development of "coordinated hospital systems."[1] At that time, the nation's hospital facilities were obsolete and unevenly distributed.

Congress enacted the Hill-Burton Hospital Survey and Construction Act in 1946. This act provided funds for states to inventory their existing hospitals and develop programs for constructing public and other nonprofit hospitals and upgrading existing facilities. Over the subsequent 20 years, this act successfully distributed funds for building and refurbishing hospital facilities. By 1974, the problem of a shortage of hospital beds had changed to a concern that there was an oversupply of beds, and Hill-Burton authority was allowed to expire.

In the 1960s, in response to the concept that the public had a right to health care, legislation was passed to make health services reimbursible by the federal government. Two titles were added to the Social Security Act of 1965. The first was Title XVIII, which established the Medicare program for people aged 65 and older. The second was Title XIX, the Medicaid program, which substantially expanded financial assistance to enable states to pay for medical services for the indigent.

In 1980, 29-million people were enrolled in Medicare at a total cost of $36-billion or $1,900 per person enrolled. In the same year, 22-million people were enrolled in Medicaid at a cost of $23-billion or $1,100 per person enrolled.[2] The cost of Medicare and Medicaid programs have continued to increase at the rate of 15 percent per year.

Expenditures for health care more than tripled between 1960 and 1972 from $26-billion to $83-billion. In the same period, the percentage of the gross national product that went to health care increased from 5.2 percent to 7.6 percent.[3] In 1983, the national health expenditure was 10.9 percent of the gross national product, a cost of $362.3-billion. At the same time, the gross national product increased by 7.7 percent. Thus, the medical component of the gross national product has been increasing at a disproportionally rapid rate.[4]

The annual expenditures for Medicare alone are projected to reach $99-billion in 1987. These projected increases caused the federal government to enact the Tax Equity and Fiscal Responsibility Act (TEFRA) in 1982, which established Medicare inpatient cost-per-case reimbursement limits.

DRGs

In an attempt to control health costs across the board, a system of sorting patients by discharge diagnosis into categories that are medically similar and have approximately equivalent lengths of stay was developed by Thomas et al at Yale. This system established diagnosis-related groups (DRGs). Then, Public Law 98-21, an amendment to the Social Security Act passed by Congress in 1983, established a prospective payment system for Medicare payments to hospitals based on DRGs.

LENWORTH M. JACOBS, M.D., M.PH., F.A.C.S., Director, Trauma Program and Ambulatory and Emergency Medical Services, Hartford Hospital, Hartford, CT; Associate Professor of Surgery, University of Connecticut Health Center, Farmington, CT.

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This legislation has had and will continue to have a profound effect on the manner in which American health care is delivered. In essence, if a hospital can render care less expensively than for the sum of money with which it is prospectively reimbursed, that hospital can use the remaining money in ways that are beneficial to the hospital. Conversely, if the care given costs more to deliver than the hospital is reimbursed, the hospital will have to decrease its payroll or its annual operating expenses in order to survive.

The DRG system of reimbursement has caused hospitals to look at themselves much more like businesses than charitable organizations. The consequences are that unprofitable lines of health care are likely to be carefully scrutinized or jettisoned. This could mean that costly programs which lose money for the hospital are likely to be rationed. Trauma care is one of these programs.

DRGs were developed from a study of actual clinical cases from 332 hospitals that were intended to represent a cross-section of all hospitals in the United States. Twenty-three major diagnostic categories and 467 diagnoses were established. One problem is that the DRGs do not distinguish among patients with different levels of intensity or severity of the same disease or disorder. Thus, even though DRG number 444, 445, and 446 are specific for multiple trauma, they do not account for the severity of the multiple injuries, and, therefore, length of stay and costs.

Hospitals that deal with the more severely injured patients will incur a major disincentive if they are reimbursed less than the cost of managing the patient. In the present changing climate of health-care delivery, for financial reasons, there may be a decreasing willingness on the part of hospital administrators to admit severely multi-system injured patients despite the surgeon's wishes. This could have a major negative impact on the care of these patients.

DRG Trauma Study

On October 1, 1983, the prospective payment system went into effect for all the hospitals in the State of Connecticut. At the same time, a prospective study was initiated at Hartford Hospital to measure the impact on trauma patients. Hartford Hospital, a 1,000 bed institution, is the largest hospital in the state and receives 13 percent of all medical admissions in the state. It is a comprehensive trauma center. Trauma patients admitted to the hospital were prospectively entered into a computerized trauma registry. The study collected demographic, physiologic, anatomic, investigational, and management information as well as data on clinical outcome, length of stay, hospital cost, and DRG reimbursement.

A total of 1,018 patients were entered into the registry between October 1, 1983 and July 31, 1984. The data were analyzed with an IBM 4341 mainframe computer and a SAS/Graph computer graphics system.

Trauma Scores were computed by the Champion methodology and Injury Severity Scores were calculated by the Baker methodology.[5, 6, 7]

The Trauma Score is a scoring system that assigns a numerical value to the patient's physiologic state. The score ranges from 16 to one. A value of 16 represents a patient with minimally deranged physiology, and a score of one represents a patient with maximally deranged physiology. This scoring system has been shown to predict the patient's chances of survival (Figure 1).

The score is derived from easily obtained physiologic parameters, such as blood pressure, respiratory rate, capillary refill, and the Glasgow Coma Scale. These elements can be obtained in the field by emergency technicians or in the emergency department.[8]

The Injury Severity Score (ISS) is a scoring system that assigns a numerical value based on the number and severity of anatomical injuries. These data are obtained after a physical exam and after radiographic and operative findings have been obtained. The score ranges from one to 75. A score of one represents minimal injury and a score of 75 represents maximal anatomical injury. Patients with a low score have a maximal chance of survival, and patients with a high score have a minimal chance of survival.[7]

The Trauma Score and the Injury Severity Score are both objective measures of the severity of a patient's injury. The scoring systems lend themselves to testing the hypothesis that hospitals are reimbursed less than their costs to manage more severely injured patients.

Figure 1

PREDICTED SURVIVAL BY TRAUMA SCORE

PERCENTAGE SURVIVAL	99	98	95	91	83	71	55	37	22	12	7	4	2	1	0	0
TRAUMA SCORE	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1

≏90% of Patients ≏10% of Patients

The data from the survey are shown graphically in the following figures:

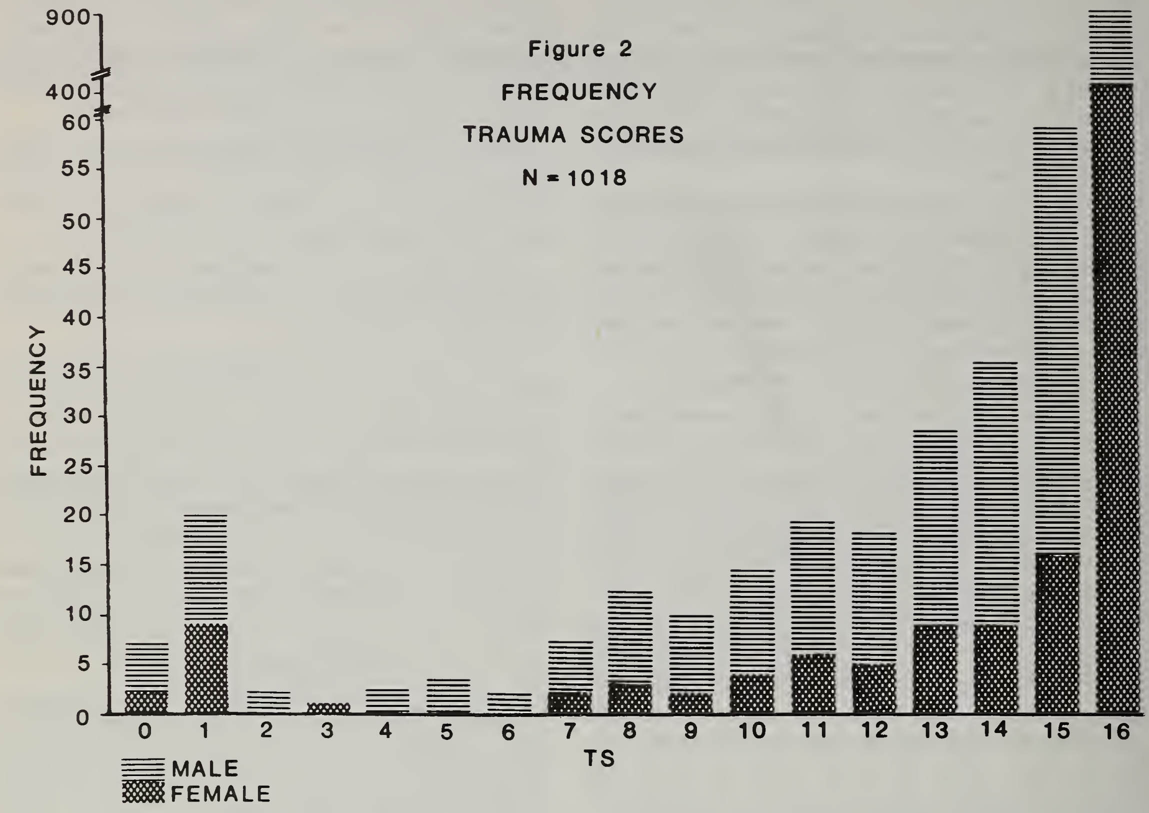

Figure 2 shows the 1,018 patients placed into each of the 16 cohorts of the Trauma Score. The majority of the patients are male and 90 percent of all patients are in the Trauma Score group 13 to 16. The predicted survival in this group ranges from 91 to 99 percent.

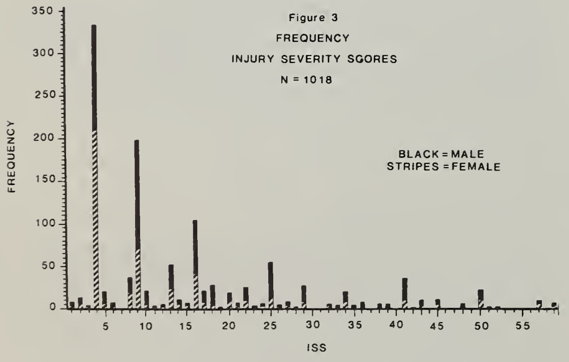

Figure 3 shows the 1,018 patients placed into each of the 75 cohorts of the Injury Severity Score.

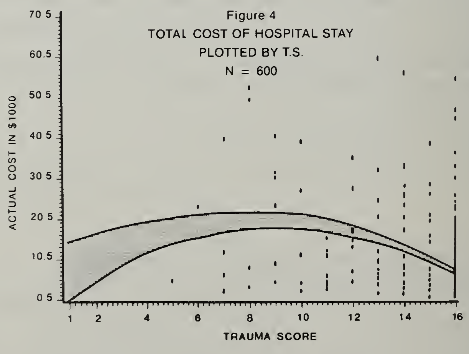

Figure 4 shows the cost in dollars for each of the patients in the 16 Trauma Score cohorts, with the mean cost displayed with one standard deviation.

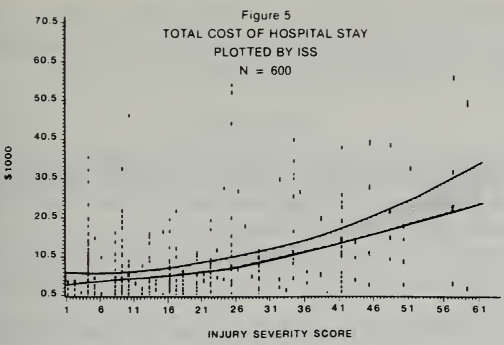

Figure 5 shows the same information as Figure 4 but for the patients distributed in the cohorts of the ISS.

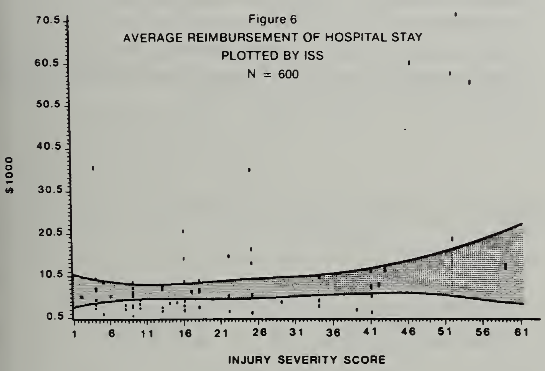

Figure 6 shows the average reimbursement to the hospital from DRGs for the patients in the cohorts of the ISS. The mean cost is displayed with one standard deviation.

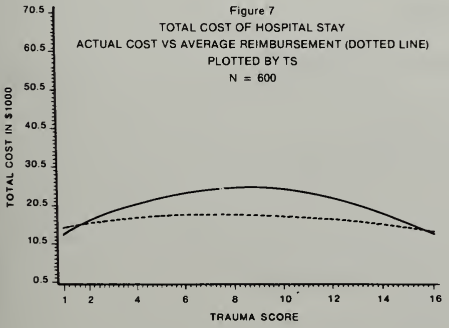

Figure 7 shows the actual cost and the reimbursement to the hospitals for all patients, reported by the Trauma Score.

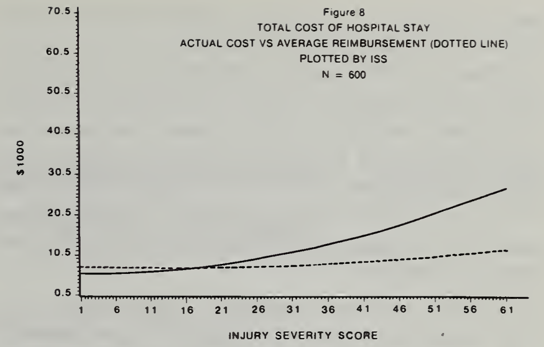

Figure 8 shows the same information reported by the ISS. The role of age is an important variable since DRGs 444, 445, and 446 and age-specific. (DRG 444—Multiple trauma, age 70 or above; DRG 445—Multiple trauma, age 18 to 69; DRG 446—Multiple trauma, age 0 to 17.)

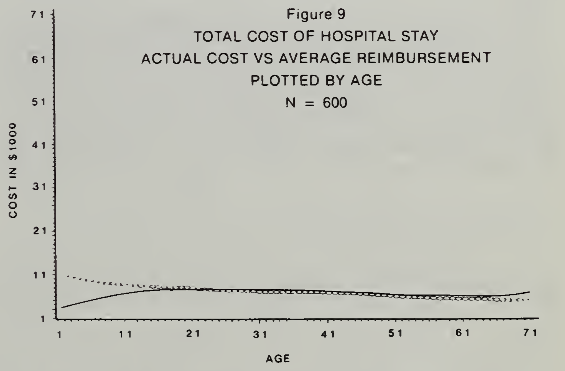

Figure 9 shows the cost and reimbursement data by age. This shows no difference in the mean values, demonstrating that age had no effect on reimbursement.

Discussion

The data from this study demonstrate both from a physiologic and anatomic perspective that more severely injured patients consume more resources. The most severely injured patients with minimal chances of survival do not consume as many resources because they die early in the course of the disease.

The data also demonstrate that it costs a hospital significantly more to manage a severely multi-system injured patient (Trauma Score 11 to 5) than the hospital is reimbursed in the DRG system. Hospitals that find other types of patient care to be more cost-effective may wish to discontinue trauma care. This will ultimately become a major disincentive to managing trauma patients. If this is allowed to occur, it will be detrimental to severely multi-system injured patients.

Potential Solution

The federal government is in the process of developing voluntary national standards for emergency health care. If these standards were designed to include outcome expectations, additional reimbursement could be given to hospitals that meet the national standards and attain the expected outcome relative to morbidity and mortality.

In March of 1984, the U.S. Department of Transportation National Highway Safety Administration convened an emergency medical services voluntary standards planning workshop and selected the American Society for Testing and Materials (ASTM) to develop national standards. In July ASTM set up a committee to define and set standards for hospitals and freestanding facilities that treat emergency patients.

The ASTM committee proposed that the American College of Surgeons standards be used for trauma centers.[9] These hospitals will have to measure up to outcome standards for the management of each level of severity of trauma patients. If these standards are achieved and maintained, there should be an increase in the DRG reimbursement to compensate for the loss the hospital will incur for appropriately managing the severely injured trauma patient.

The financial climate and governmental need to contain health-care costs has led to an attempt to generate rational plans for emergency medical services through the development of voluntary standards. This has the potential to generate fiscal incentives for hospitals that demonstrate competence in the management of severely traumatized patients. It is important that surgeons who are interested in maintaining excellent care for trauma patients be informed and involved in this process.

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Status Report on the Acquired Immunodeficiency Syndrome

Human T-Cell Lymphotropic Virus Type III Testing

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Human T-cell lymphotropic virus type III (HTLV-III) is a retrovirus that is currently accepted as the primary cause of the acquired immunodeficiency syndrome (AIDS). Serologic assays have been developed to detect the presence of antibody to HTLV-III; the presence of such antibodies is taken as reasonable proof of past or present infection with this agent. These assays have been used for epidemiologic studies and to screen defined populations and recently have been introduced for the screening of donated blood.

Recently the Food and Drug Administration (FDA) approved three test kits, manufactured by Abbott Laboratories, North Chicago, Ill, Electro-Nucleonics Inc, Fairfield, NJ, and Litton Bionetics, Charleston, SC, for screening donated blood and plasma for antibodies to HTLV-III. These kits utilize the enzyme-linked immunosorbent assay (ELISA) technique to detect antibodies to HTLV-III, which utilizes beads or microtiter wells coated with antigens obtained from disrupted whole virus grown in the human leukemic cell line, H9. The test serum is incubated with the antigen-coated surface; then, following serum removal and appropriate washing, goat anti-human (IgG) immunoglobulin linked to an enzyme (horseradish peroxidase) is added and the test is reincubated. During this incubation period the goat antibody combines with any human IgG antibody that was bound to viral (and cellular?) antigens during the first incubation period. After removal of the goat antibody and washing of the wells or beads, a substrate (*o*-phenylenediamine or azinobenzthiazolium sulfonate) is added and is acted on by the enzyme to produce a color, the intensity of which is proportional to the amount of human antibody binding to the HTLV-III antigens. The amount of color developed is read spectrophotometrically. A cutoff absorbance value is established by comparison with known positive and negative serum controls. Placing of the cutoff values affects both the sensitivity and specificity of the test.

At the moment there is no standard reference antiserum ("gold standard") against which all test antisera may be measured. Therefore, the sensitivity and specificity of the ELISA test have been defined operationally. (For the ELISA test, *sensitivity* has been defined as true-positives/true-positives + false-negatives, and *specificity* as true-negatives/true negatives + false positives).[1] The sensitivities and specificities of these three test kits are shown in the Table; each of the manufacturers conducted its own clinical study, which formed the basis for the computation of the sensitivities and specificities shown.

These kits employ a 96-well microtiter plate and, in the initial test, a single dilution of test serum is tested in a single well. Following the initial test, the manufacturers

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From the Council on Scientific Affairs, Division of Scientific Activities, American Medical Association, Chicago.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of June 1985.

Reprint requests to Division of Scientific Activities, Council on Scientific Affairs, American Medical Association, 535 N. Dearborn St., Chicago, IL 60610 (John C. Ballin, PhD).

specify that the ELISA test be repeated in duplicate (ie, two wells instead of one) with the same serum sample and the same dilution. A positive test results when at least one of the two test wells is positive. None of the kits includes an uninfected cell control HLA-DR4 antigen has been identified in two of these kits.[2]

SENSITIVITIES, SPECIFICITIES, AND EXPECTED FALSE-POSITIVE RATES FOR THREE HTLV-III ANTIBODY TEST KITS*

			Expected False-Positives§ When Antibody Prevalence Is	
Manufacturer	*Sensitivity†*	*Specificity‡*	*0.1%*	*1.0%*
Abbott Laboratories	93.4%	99.8%	68	17
Electro-Nucleonics Inc	99.6%	99.2%	89	44
Litton Bionetics	98.9%	99.6%	80	29

*HTLV-III indicates human T-cell lymphotropic virus type III. Statistics are those provided by the manufacturers in their current package inserts.

†Assuming a 100% prevalence of HTLV-III antibody in patients with acquired immunodeficiency syndrome.

‡Assuming a zero prevalence of HTLV-III antibody in random donors.

§Out of every 100 reactive samples in the enzyme-linked immunosorbent assay.

A recent FDA communication recommended that all blood products with an initial reactive test result should not be distributed for transfusion or further manufacturing into injectable products. However, the FDA also recommended that donors should not be notified of positive test results until there is clear agreement between initial and repeated ELISA tests.

It has been suggested that when the results from ELISA tests are judged to be uncertain, additional testing be performed on the same serum sample by the Western blot technique. In this technique, viral antigens (from disrupted virions) are separated by polyacrylamide-gel electrophoresis and then transferred ("blotted") to nitrocellulose paper. The transferred viral antigens are then exposed to the test serum and any specific antibodies present react with the specific antigen bands. Thus, with this technique, antibodies to specific proteins associated with HTLV-III are identified. The minimal criteria for defining a positive Western blot test have not been firmly established. In an earlier communication the Public Health Service suggested that the test be considered positive if antibody to band p24 or p41 is detected.

While the Western blot technique has high specificity, it is generally considered to be less sensitive than the ELISA test, for more antibody is required to result in a positive test. Also, the test has not been standardized and varies in sensitivity from laboratory to laboratory. Thus, there would be a tendency toward false-negative results with low-titered serum samples and, with such serum samples, the clarification hoped for with the Western blot test may not be realized.

The HTLV-III ELISA test has recently been introduced for screening blood and it will be used extensively in the field. Presently there are uncertainties surrounding the clinical meaning of a positive test and concerning the incidence of true- and false-positive results. It is known that the number of true-positive results in a population varies not only with the prevalence of antibody in that population but also with the sensitivity and specificity of the test kit employed (Table). Also, one would expect that the incidence of true-positive results will vary according to the incidence of AIDS among the different risk groups, being highest for homosexuals and lowest for those not in any risk group. The clinical significance of a positive ELISA test on a single serum sample from an asymptomatic donor not belonging to any AIDS risk group is unknown.

At the present time approximately 20 million units of blood and plasma are processed annually in the nation in blood banking and plasma collection facilities. Assuming a 0.1% prevalence rate of HTLV-III antibody in the general population, and with the sensitivity and specificity of the Abbott Laboratories HTLV-III ELISA kit, for example, it can be estimated that, on a national level, this would translate into approximately 20,000 positive test results, of which 13,600 (20,000 ff 0.68) may be false-positive results. (This statistical calculation may be high; there have been opinions expressed that the false-positive rate may only be 10% or less. Also, the incidence of HTLV-III antibody in the first 100,000 units of donated blood collected and screened by the American Red Cross was 0.22%.) These figures assume that all potential donors who are members of high-risk groups are either self-deferred or deferred through additional intake processes. In addition, it is likely that there will be a large number of persons who will have been determined to have a positive HTLV-III test from alternative testing sites (ie, sites other than blood collection sites where HTLV-III antibody testing is performed). The number of positives (true and false) resulting from alternative testing sites may be in the tens of thousands, if not 100,000 or more. (Estimates have been made that the number of HTLV-III-infected persons in the United States today currently exceeds 300,000.)

Ultimately all positive reactors will be referred to practicing physicians. The practitioner will be expected to determine the significance of a positive test result, offer sagacious medical counseling on a fatal and incurable disease, and do follow-up studies on a disease that has an incubation period of up to five years. The vast majority of physicians have never seen a case of AIDS, and most are unfamiliar with the management of the disease.

In March of this year the FDA sent a "Dear Doctor" letter to all physicians in the United States. Included with this mailing was some important AIDS information concerning recommendations for individuals with HTLV-III-positive antibody results and a "Clinicians Guide to Evaluation of HTLV-III Antibody-Positive Individuals." These recommendations, however, do not distinguish between high-risk and low-risk individuals with repeated positive HTLV-III antibody results. At a consensus conference convened by the Association of State and Territorial Health Officials (ASTHO) such recommendations were developed and are included at the end of this report. (Copies of the ASTHO publication, *Guide to Public Health Practice: HTLV-III Screening in The Community,* may be obtained by contacting the executive director, ASTHO Foundation, Suite 207, 10400 Connecticut Ave., Kensington, MD 20895.)

The entire genome of HTLV-III has been cloned in bacteria in at least three commercial laboratories (Centocor, Malvern, Pa, Genetic Systems Corp, Seattle, and Chiron, Emeryville, Calif). Second-generation screening tests utilizing viral proteins made by genetic engineering techniques in bacteria, instead of whole virus grown in human lymphoid cell cultures, are being developed. It is hoped that these new tests will be not only cheaper, but more sensitive and specific than currently employed tests. The first of these second-generation tests is not expected to be approved by the FDA for at least a year.

The Council on Scientific Affairs will continue to monitor developments in HTLV-III testing, as well as in the other areas of AIDS research, and periodically will inform the membership of its evaluations and recommendations.

Recommendations for Persons with Repeated Positive Test Results

(These have been excerpted with permission from the brochure: *Guide to Public Health Practice: HTLV-III Screening in the Community.* Kensington, Md, Association of State and Territorial Health Officials Foundation, March 1985.)

Follow-up Recommendations for High-Risk Individuals with Repeated Positive Test Results

State and local health departments are urged to work with blood banks, plasma centers, private providers, community organizations, and others providing HTLV-III testing to ensure that high-risk individuals be advised to establish a relationship with a physician who can, by reason of training and experience, continue to evaluate the patient for signs and symptoms of AIDS or related conditions. High-risk individuals are defined as persons with known risk of exposure to HTLV-III, or at high risk of acquiring or transmitting the HTLV-III virus. This group includes all men who have had sexual contact with another man, intravenous drug users, hemophiliacs, and other persons who have had sexual contact with a person who has had an HTLV-III infection or who is at increased risk of exposure to HTLV-III. It is also recommended that:

1. High-risk individuals be advised of the early clinical manifestations of HTLV-III infection, AIDS, and AIDS-related conditions and advised to seek immediate medical attention if any of them occur.
2. High-risk individuals be advised that the prognosis of an individual infected with HTLV-III (the probable cause of AIDS) over the long term is not known. However, available studies conducted among homosexual men indicate that most persons will remain infected, but asymptomatic
3. High-risk individuals be advised to seek medical evaluation and follow-up at least twice annually, and more frequently as indicated for an individual who develops signs or symptoms suggestive of HTLV-III infection, AIDS, or AIDS-related conditions.
4. High-risk individuals be advised that although the person may be asymptomatic, there is a risk of infecting others by sexual intercourse, sharing needles, and possibly through saliva or exposure through oral-genital contact or intimate kissing. The efficacy of condoms in preventing infection with HTLV-III is unproved, but the consistent use of them may reduce transmission.
5. High-risk individuals be advised that blood, plasma, body organs, other tissue, or sperm should not be donated.
6. High-risk individuals be advised that toothbrushes, razors, or other implements that could become contaminated with blood should not be shared.
7. High-risk individuals be advised that children born since 1979 to women with a positive HTLV-III test should be clinically evaluated.
8. High-risk individuals who are women, or women who have a high-risk sexual partner who has a positive test, be advised that they are at increased risk of acquiring AIDS, and that any offspring is at increased risk of acquiring AIDS. (Because there was no current consensus on recommendations 8 and 15, these decisions should be left to the discretion of the evaluating physician.)
9. High-risk individuals be advised that in the absence of close or intimate contact, household contacts need not be referred for testing at this time.
10. High-risk individuals be advised that after accidents resulting in bleeding, contaminated surfaces should be cleaned with household bleach freshly diluted 1:10 in water.
11. High-risk individuals be advised that devices that have punctured the skin, such as hypodermic and acupuncture needles, should be steam-sterilized by autoclave before reuse or safely discarded. Whenever possible, disposable needles and equipment should be used.
12. High-risk individuals be advised that when seeking medical or dental care for illness, they should inform those responsible for their care of the positive HTLV-III results so that appropriate evaluation can be undertaken and precautions taken to prevent transmission to others.
13. High-risk individuals be advised that most persons with positive HTLV-III test results need not consider a change in employment. However, those persons whose work involves significant potential of exposing others to his or her blood or other body fluids

should, at a minimum, be advised to act prudently and take precautions such as wearing gloves.

14. High-risk individuals be advised than when they are employed in medical, dental, or other health care professions and performing invasive procedures or if they have skin lesions, they should take precautions similar to those recommended for hepatitis B to protect their patients from the risk of infection.
15. High-risk individuals be advised that any sexual or needle-sharing partner of a person with a positive test should be advised to seek clinical evaluation of potential risk factors, symptom history, and physicial findings. (Because there was no current consensus on recommendations 8 and 15, these decisions should be left to the discretion of the evaluating physician.)

Follow-up Recommendations for Low-Risk Individuals With Repeated Positive Test Results

State and local health departments are urged to work with blood banks, plasma centers, private providers, community organizations, and others providing alternative testing and counseling sites to ensure that low-risk persons with repeated positive HTLV-III antibody tests be provided with counseling. These persons are defined as those with repeated positive results who are not members of known risk groups, have no signs or symptoms of immune deficiency disease, and have normal results on physical and laboratory examination. It is recommended that:

1. Low-risk individuals be advised about interpretation of these test results. This should include an understanding that the prevalence of false-positive results in the low-risk group may be high, and that the patient's particular result may be of questionable significance. The person should also understand that a positive test—if it is not a false-positive result—measures only antibodies to the virus, which may indicate past or present exposure to HTLV-III or a related virus. In addition, the person should be counseled that he/she does not appear to have AIDS, and that the risk of developing AIDS in the future, if the test result is not falsely positive, is small.
2. Low-risk individuals be advised that, as a precautionary measure, they should not donate blood, plasma, sperm, or body organs.
3. Low-risk individuals be advised that if no known risk factors are present, currently there is insufficient evidence to warrant a broad restriction on sexual relations. However, advice on sexual relations and practices should be individualized.
4. Low-risk individuals be advised that until more is known about the status of a positive test result in a low-risk population, that testing the patient's regular sexual partner may provide better or more information to determine if the test result may be a true- or false-positive result. However, testing of other family members of low-risk patients is not advised.
5. Low-risk individuals be advised that there is insufficient evidence to warrant advising blanket postponement of pregnancy at this time. However, each circumstance should be carefully evaluated.
6. Low-risk individuals be advised that they should notify their personal physicians and dentists that they have had repeated positive HTLV-III screening test results but were considered as having no known risk of exposure to AIDS.
7. Low-risk individuals be advised there is no need for any restrictions on employment, education, or other social contacts.
8. Low-risk individuals be advised that additional counseling or referral is available if they have further questions or concerns.
9. Low-risk individuals be advised to seek medical follow-up assessment within six months in order to identify any potential changes in their medical status or recommendations.

The nine preceding recommendations apply only to individuals who have no abnormal physical or laboratory findings other than repeated positive HTLV-III test results, and are not in a known risk group for acquiring AIDS. All other individuals with repeated positive HTLV-III tests, whether with known risk factors (including being a sexual partner of a person in a high-risk group) but otherwise free of findings, or with no known risk but some clinical findings, should be counseled as "high-risk" patients. There will be cases where low-risk individuals desire to know all recommended precautions concerning the transmission of HTLV-III infection, AIDS, and AIDS-related conditions. In these cases, it is suggested that the recommendations for high-risk individuals also be given to the individual. In addition, where the individual clinician is uncertain as to the risk status of the person who has been tested, it is suggested that both sets of recommendations be given to the individual.

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Surrogate Motherhood and the Law

SHEILA TAUB, J.D.

Infertility is estimated to afflict approximately one out of six couples in the United States today. Those infertile couples who wish to adopt a child are finding it increasingly difficult to do so because the availability of abortion and the lessened stigma facing unwed mothers who decide to keep their babies has greatly diminished the number of adoptable babies. To be sure, there are many children awaiting adoption, but those most in demand—healthy, white, newborns—are in short supply.

A novel method of reproduction has recently arisen to satisfy the desire of some infertile couples to become parents: surrogate motherhood. In the typical surrogate motherhood arrangement, a married couple who cannot bear a child because of the wife's inability to conceive or to carry a child to term contracts with another woman, the surrogate (who may be married or single), to have the surrogate artificially inseminated with the sperm of the husband of the infertile couple. The surrogate agrees that if she conceives as a result of this insemination and bears a child she will relinquish the child to the infertile couple shortly after its birth. In most cases, the surrogate is paid a fee of about $10,000 if she fulfills all the provisions of the agreement. To date, over 100 children have been produced by this method. Its legality is open to considerable question, however, for reasons which this article will attempt to explain.

The technique of artificial insemination which is used in surrogate motherhood has been used since the 19th century to enable couples to bear a child when the fertility problem resides in the husband. Currently it is estimated that over 10,000 children are conceived annually by artificial insemination of women whose husbands are infertile. Usually, the sperm is that of an anonymous donor, who is paid a small fee for supplying the sperm. In a few cases, the husband's own sperm may be used after having been treated to increase its fertility. Artificial insemination by donor has presented few legal controversies to date, possibly because the procedure is usually surrounded by secrecy, with only the couple and their physician being aware of the fact that it was used.

The technical procedure involved in surrogate motherhood is identical to that involved in artificial insemination by donor, namely, a woman is artificially inseminated with sperm from a man who is not her husband, but the purpose of the procedure, the intentions of the parties, and the legal status of the arrangement are all vastly different. Indeed, many of the laws passed to facilitate artificial insemination present significant legal obstacles to the enforcement of surrogate motherhood agreements. About half the states, including Connecticut, have statutes governing artificial insemination, which typically provide that a man who donates sperm to a woman who is not his wife is not the legal father of the child, and that the woman's husband will be considered the legal father if he has consented to the insemination. The child born of artificial insemination is considered the legitimate offspring of the husband and wife, with the same rights as a child conceived naturally. The same result has been achieved by judicial decisions in a number of states which have not yet enacted statutes on the subject. In addition, all states have a presumption that a child born to a married couple is the legitimate offspring of the husband and wife, a presumption which may, however, be rebutted by evidence to the contrary obtained from blood- or tissue-typing.

In both artificial insemination and surrogate motherhood, a couple who are having trouble conceiving because of the infertility of one of them enlists the assistance of a third party, for a fee, to enable them to have a child which is genetically the offspring of the fertile member of the couple and the third party. The resemblance between the two procedures has led a number of legal commentators to state that if artificial insemination is legal and proper, then surrogate motherhood should be as well, and that it might even be unconstitutional to treat the two differently. That argument is unpersuasive to this author, among others. There is a vast difference between the physical and emotional investment made by the sperm donor in artificial insemination compared to that made by the surrogate mother. This difference (which is only partially reflected in their current rates of compensation: considerably less than $100 for the sperm donor, versus $10,000 for the surrogate mother) provides ample justification for different legal treatment of the two procedures.

SHEILA TAUB, J.D., Professor of Law, University of Bridgeport School of Law, Bridgeport, CT.

There is widespread agreement, even among those who are in favor of surrogate motherhood arrangements, that the typical surrogate motherhood contract would not be enforceable in any state in the country today. This is in part because it obligates the surrogate to perform services of a very personal nature, and courts have traditionally been reluctant to order specific performance of contracts for personal services. Thus if the surrogate were to breach the contractual provisions to undergo the artificial insemination, to obtain medical care during the pregnancy, or to refrain from activities that might be harmful to the fetus, a court would be unlikely to order her to abide by those provisions. It might order her to pay money damages to the other parties to the contract for the breach, but that would hardly compensate them for what they have lost.

If the contract provides that the surrogate must either refrain from having an abortion, or have an abortion if there is evidence that the fetus is defective, a court would be highly unlikely to order compliance with such a provision, given the fact that the Supreme Court has held, in Roe v. Wade,[1] that the right of a woman to decide whether or not to have an abortion is a fundamental right implicit in the constitutional right of privacy.

If the surrogate refuses to give up the child, a court is unlikely to order her to do so, at least absent a finding that she is an unfit mother. Again, money damages would not compensate the couple for the loss of the child. Conversely, if the surrogate were willing to give up the child, but the couple did not wish to accept it (if the child were grossly defective, for example, as happened in the notorious Malahoff case featured on the Phil Donohue show), it is not at all certain that the court would order it to do so.

The surrogate motherhood contract may be illegal, as well as unenforceable, in many states. The provision that the child will be adopted by the wife of the sperm donor, in conjunction with the provision of fees to be paid to the surrogate and to the attorney who arranges the transaction, may run afoul of statutes prohibiting baby-selling, the arrangement of adoptions prior to the birth of the child, and the arrangement of adoptions other than through an authorized adoption agency.

Laws against baby-selling were passed as a result of the 1955 Kefauver hearings on commercial trafficking in children, which disclosed that prostitutes were being used as surrogates. Today, all states make baby-selling a crime. The question of whether or not to prohibit surrogate motherhood should not turn on whether we choose to label it baby-selling, but rather on the possible harmful consequences to the parties involved. However, if one is forced to answer the question, "Is surrogate motherhood babyselling, or is it a contract for the services involved in being pregnant and delivering a child?" one has only to look at the compensation provisions in one typical surrogate motherhood contract: If the surrogate miscarries before the fifth month of pregnancy, she gets no compensation; if she miscarries, or if the baby dies or is stillborn after the fourth month, she gets only $1,000. Only if she turns over a live baby to the adopting couple does she receive the full $10,000 that she was promised.

Even if a surrogate motherhood agreement does not violate any state law, a court could still find it illegal on the grounds that it is against public policy.

Specific legislation would be required to render surrogate motherhood agreements both legal and enforceable. As of January, 1985, no state had enacted legislation either specifically permitting or prohibiting surrogate motherhood agreements, but legislation was under consideration in 21 states and the District of Columbia.[2] Three states (Alabama, Kentucky, and Oklahoma) and the District of Columbia were thinking of prohibiting surrogate motherhood agreements. Two (Missouri and Ohio) were still neutral, but 15 states were considering their legalization (Alaska, California, Connecticut, Hawaii, Illinois, Kansas, Maryland, Massachusetts, Minnesota, New Jersey, New York, Oregon, Rhode Island, South Carolina, and Virginia). Michigan had strong advocates on both sides of the issue.

Of the bills permitting surrogate motherhood, most did not require the sperm donor to be the husband of an infertile wife, and many would have allowed single persons of either sex to adopt the resulting child. The latter would enable a single man to become a father by contracting with a surrogate, and the former would allow a wife who does not want to take the time out from her career for preg-nancy and childbirth to obtain a child that is biologically her husband's but not hers. (If the technology advances sufficiently to permit the transfer of a fertilized ovum from the wife to the surrogate, who can then gestate it for the duration of the pregnancy, the child could then be genetically the offspring of both the husband and the wife.)

Most (but not all) bills required that the surrogate be 18 or older. Most contained a detailed list of provisions required to be included in the surrogate motherhood contract, including pre-insemination medical and psychological screening of the surrogate. Most would not pay the surrogate unless a live child is provided for the sperm donor or other adoptive parent. The New Jersey bill would limit the fee to $10,000, but other bills would set a $10,000 minimum for the payment to the surrogate. One can readily envision the rapid escalation of fees requested by potential surrogates possessing such desired attributes as a high I.Q., great musical or athletic ability, or outstanding good looks.

Six states would require a home study similar to that done in adoption, but would leave the final decision to a court. Since a particular court might have neither the inclination nor the means to investigate the suitability of the couple to raise the child, there would be little control over the quality of the home the child is going to. (Of course, this is always the case when children are conceived naturally, but the greater physical and emotional investment of the natural parents may arguably lead to a greater concern for the welfare of the child.)

Several bills require that a court be notified when pregnancy has occurred, setting in motion certain actions to legitimize the child and terminate the parental rights of the surrogate. Several bills require testing for paternity after the birth of the child. Under most bills, the surrogate mother can object to termination on grounds that the sperm donor is not the father or that adoption would not be in the child's best interests. All but two bills (those of California and Michigan) provide for confidentiality. Violation of any provision of these bills is usually a misdemeanor, and there are few penalties for violation.

Which of the three possible options available to state legislatures with respect to surrogate motherhood should be exercised at the present time: legalization, criminalization, or neither action? As a practical matter, the strong emotions aroused on both sides of the issue may prevent the rapid enactment into law of any of the pending bills, but some of the arguments for and against each of the three options will now be explored.

Arguments against having the legislatures do nothing and letting the courts decide the issue of the legality of the surrogate motherhood contract are, first, that it might lead to inconsistent decisions in different courts, and second, that courts are ill-suited to deciding complex questions of social policy because they lack the fact-finding abilities of legislative bodies and may not see all the potential ramifications of their decisions when they are asked to decide what may be a very atypical case. (For example, in one surrogate motherhood case, the surrogate refused to relinquish the child to the married couple, in which the wife was reportedly a transsexual.) This author feels that legislation at this time would be premature, since surrogate motherhood has only been practiced on an appreciable scale for less than a decade, and therefore we do not yet know enough about its potential consequences to be able to legislate wisely. The legislature can always act, after seeing the kinds of cases that are brought to the courts, if it is not happy with the judicial resolution of those cases.

One argument against prohibition or criminalization of surrogate motherhood is that people who are desperate for a child will enter into such arrangements anyway, and society should not make criminals out of them. The counterargument is that if the legislature believes the practice to be harmful, criminalizing it would at least discourage many people from engaging in it.

A second argument against prohibition is that for those who choose to engage in the practice despite its illegality, there will be many unanswered questions concerning the legal rights and obligations of the parties involved, perhaps the most significant being the question of the parenthood of the resulting child. For those who encounter no problems, nothing is lost. Where a problem arises, it will usually be because either nobody wants the child, or because both the sperm donor and the surrogate mother want the child. In either case, the parties can resort to a court, which will presumably try to do justice for the parties, while being guided by the same principle of doing what is in the best interests of the child that is applied in other kinds of custody litigation.

Perhaps the most critical argument against prohibition of surrogate motherhood agreements is that it would be unconstitutional, because the United States Supreme Court has stated, in cases involving abortion, contraception, and sterilization, that the constitutional right to privacy encompasses a person's decision whether or not to bear a child. A number of legal commentators have expressed the view that this right of privacy in procreational decision-making extends to surrogate motherhood and other novel methods of producing a child. Others, including this author, do not share that view. The Supreme Court may have made some broad statements in the abortion, contraception, and sterilization cases, but the actual issues that they decided in those cases were quite narrow. In Roe v. Wade, the court decided that a state could not prohibit abortion entirely, but could impose reasonable restrictions on the right to an abortion, depending on the stage of pregnancy. In Skinner v. Oklahoma,[3] the court stuck down a compulsory sterilization law. In Griswold v. Connecticut,[4] it recognized a constitutional privacy right of married couples to use contraceptives, and in Eisenstadt v. Baird,[5] it extended this right to unmarried couples. Thus the Supreme Court procreation cases to date safeguard a woman's or a couple's right to decide not to have a child and prohibit the state from impairing a person's biological ability to have a child. This is a far cry from saying that an individual has a constitutional right to bring children into the world by novel technological means, some of which were unknown to members of the court when they rendered the above decisions.

Even if the court decides that people do have that right, states could still impose certain restrictions on the utilization of the new fertility technology. If the Supreme Court were to decide that the right to procreate by any means whatever is a fundamental right, those restrictions would have to be justified by a compelling state interest. A state could meet that standard by demonstrating sufficient harm to the parties, to the institution of the family, or to society. If the Supreme Court were to decide that the ability to use the new fertility technology is not a fundamental right, a state would only have to demonstrate a rational basis for legislation restricting access to it, an easier standard to meet.

What harm could result to the parties affected by a surrogate motherhood agreement that might justify the state's prohibiting or restricting access to such agreements? The child may, on learning of his origins, suffer from a feeling of rejection by his biological mother, and may wonder if his adoptive mother would also be willing to give him up if paid a sufficient fee. He or she may feel the same loss of identity that many adoptive children are said to feel. A child born to a surrogate and relinquished to an unmarried man may suffer from the absence of a mother his entire life. A child given to a couple in which the wife did not wish to take time or energy from her career to devote to pregnancy and childbirth may wonder how much his adoptive mother really wanted him. If the surrogate has other children who are aware of her pregnancy, they may wonder if she would be willing to give them away as well.

The parents may suffer from feelings of guilt or inadequacy at having had to resort to this unorthodox method of producing a child, and may take their feelings out on the child in some way. Both parents may feel that the child belongs more to the father, whose sperm helped to create it, than to the mother, who merely adopted it.

The person who predictably will suffer the most, psychologically as well as physically, is the surrogate mother. That term is misleading, probably deliberately so, because the so-called "surrogate" is the natural, biological, genetic, and gestational mother of the child. One can anticipate that on relinquishing the child to the adopting couple she will experience feelings of loss, depression, guilt, and possibly anger at the other parties to the transaction. All of these reactions were found among a group of thirty surrogate mothers who had delivered and relinquished the children.[6] Three surrogates were sufficiently distressed to seek psychiatric help, but many more displayed the above reactions to varying degrees. Ten other surrogates refused to speak with the researcher at all, so one can only speculate about their reactions to the experience. If surrogate motherhood were designated a scientific experiment which required the approval of an institutional review board, it would never pass muster under the stringent federal regulations for the protection of human experimental subjects on the basis of these data.

The surrogate can also experience harmful physical effects of her pregnancy and delivery, up to and including death. She might find it impossible to bear a child of her own in the future, either as a result of the first pregnancy, or as a result of some intervening cause. Is $10,000, or any amount of money, adequate compensation for those eventualities? Some have argued that legislators should not concern themselves with such questions provided the potential surrogate is an adult who has given her fully informed consent to the arrangement. One wonders whether a truly informed consent can be achieved in the surrogate motherhood arrangement: Can a woman who has never relinquished a child fully appreciate the emotions she will experience on doing so at the end of her pregnancy? The notion that the surrogate has given informed consent is belied by the fact that in at least two cases women were used as surrogates who had never given birth to a child. These women could have no appreciation of the physical and emotional effects of pregnancy and delivery, not to mention relinquishment of the child.

If surrogate motherhood is legalized, there is a danger that economically distressed women will see it as a viable method of augmenting their income. They may even be subjected to pressure from their husbands, boyfriends, or relatives to enter into such arrangements. To those who argue that women who become surrogates do so not because of the fee involved, but for humanitarian reasons (the desire to give an infertile couple a child) or because they enjoy being pregnant, one answer may be to legalize the arrangement, but prohibit the payment of any fee to the surrogate beyond expenses actually incurred in the pregnancy and delivery.

At present, the cost to the couple of the surrogate motherhood arrangement is approximately $25,000, of which $10,000 goes to the surrogate and about $15,000 goes to the couple's lawyer. While much of the $15,000 covers expenses (physical and psychiatric examinations of the parties, the artificial insemination, administrative expenses, etc.) there remains a sizable fee for the lawyer who brokers the arrangement. Some of the pressure for legalization of surrogate motherhood agreements may be coming from lawyers who see this as a potentially lucrative business.

Opposition to surrogate motherhood is widespread in the United States and abroad. The National Committee for Adoption, Inc. is strongly opposed to surrogate motherhood, for obvious reasons. In England, the Warnock Commission was against it and wanted it criminalized. This author's position is that the preferable course of action at the present time would be either to do nothing, and await more information about the problems and pitfalls of surrogate motherhood based on actual experiences with it, or else prohibit the payment of any fee to the surrogate beyond expenses incurred. Legalization at this time would be premature, for the reasons cited above.

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Lower Court Ordered to Drop Murder Charges Against Physicians

COURT OF APPEAL OF THE STATE OF CALIFORNIA

In these consolidated proceedings we consider petitions for writs of prohibition pursuant to Penal Code section 999a filed by two medical doctors who are charged in a complaint, now pending before a magistrate in the Los Angeles Judicial District, with the crimes of murder and conspiracy to commit murder—both felonies.

At the close of a lengthy preliminary hearing the magistrate ordered the complaint dismissed. On motion of the People, pursuant to Penal Code section 871.5, the superior court ordered the magistrate to reinstate the complaint. These proceedings followed. We issued the alternative writ, calendared the matter and heard oral argument. We have concluded that the peremptory writ should issue.

Deceased Clarence Herbert underwent surgery for closure of an ileostomy. Petitioner Robert Nejdl, M.D., was Mr. Herbert's surgeon and petitioner Neil Barber, M.D. was his attending internist. Shortly after the successful completion of the surgery, and while in the recovery room, Mr. Herbert suffered a cardio-respiratory arrest. He was revived by a team of physicians and nurses and immediately placed on life support equipment.

Within the following three days, it was determined that Mr. Herbert was in a deeply comatose state from which he was not likely to recover. Tests and examinations performed by several physicians, including petitioners herein, each specializing in relevant fields of medicine indicated that Mr. Herbert had suffered severe brain damage, leaving him in a vegetative state, which was likely to be permanent.

At that time petitioners informed Mr. Herbert's family of their opinion as to his condition and chances for recovery. While there is some dispute as to the precise terminology used by the doctors, it is clear that they communicated to the family that the prognosis for recovery was extremely poor. At that point, the family convened and drafted a written request to the hospital personnel stating that they wanted "all machines taken off that are sustaining life" (sic). As a result, petitioners, either directly or as a result of orders given by them, caused the respirator and other life-sustaining equipment to be removed. Mr. Herbert continued to breathe without the equipment but showed no signs of improvement. The family remained at his bedside and requested of the nursing staff that Mr. Herbert not be disturbed. They even objected to certain routine procedures followed by hospital personnel in caring for comatose patients.

After two more days had elapsed, petitioners, after consulting with the family, ordered removal of the intravenous tubes which provided hydration and nourishment. From that point until his death, Mr. Herbert received nursing care which preserved his dignity and provided a clean and hygienic environment.

The precise issue for determination by this court is whether the evidence presented before the magistrate was sufficient to support his determination that petitioners should not be held to answer to the charges of murder (Pen. Code, § 187) and conspiracy to commit murder (Pen. Code, § 182).

As we will later discuss, this issue must be determined against a background of legal and moral considerations which are of fairly recent vintage and which as a result have not, in our opinion, been adequately addressed by the Legislature.

In *Self v. General Motors Corp.* (1974) 42 Cal. App. 3d 1, at page 7, Justice Fleming observed that "prosecution of a lawsuit is a poor way to design a motor vehicle." By analogy it appears to us that a murder prosecution is a poor way to design an ethical and moral code for doctors who are faced with decisions concerning the use of costly and extraordinary "life support" equipment.

Murder is the *unlawful* killing of a human being, . . . with malice aforethought." Malice may be express

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This is the decision of the Second Apellate District Court of Appeal of the State of California ordering that murder charges against Neil Leonard Barber, M.D. and Robert Joseph Nejdl, M.D. be dropped, reversing a superior court order.

EDITOR'S NOTE: *Most of the legal citations are omitted.*

or implied. It is express when there is an intent *unlawfully* to take any life. It is implied when the circumstances shown an abandoned and malignant heart.

The magistrate who heard the evidence made written findings of fact and concluded that (1) petitioners did not "kill" the deceased since their conduct was not the proximate cause of death—the proximate cause (the principal cause listed on the death certificate) being diffuse encephalomalacia, secondary to anoxia, (2) the petitioners' conduct under the circumstances, being the result of good faith, ethical and sound medical judgment, was not unlawful, and (3) the petitioners' state of mind did not amount to "malice."

The superior court judge, as he was required to do under the statute before ordering reinstatement of the complaint, concluded *as a matter of law* that petitioners' conduct, however well motivated, and however ethical or sound in the eyes of the medical profession, was, under California law, "unlawful." This conclusion was reached despite his determination that the magistrate's findings were supported by substantial evidence.

The judge opined that, since everyone, sooner or later will die, homicide is simply the shortening of life by some measurable period of time and inasmuch as the petitioners' intentional conduct, which shortened Mr. Herbert's life, was not authorized by law, it constituted murder.

Of course the term homicide simply connotes the death of an individual at the hands of another. In any homicide the end result is the same—the death of a human being. Whether or not a homicide is punishable as a crime in the first instance, and the degree of punishment which is imposed in the case of a criminal homicide depends upon the mental culpability of the person causing the death.

The term "malice" is an amorphous and ill-defined state of mind which the law considers sufficiently culpable to make an unlawful killing murder rather than some lesser form of criminal homicide such as manslaughter. While the law is settled that motive is irrelevant to a determination of whether a killing amounts to murder, the lack of precision in defining malice often makes it difficult to disentangle motive from a determination of what constitutes malice.

For the purposes of this decision, however, we accept the superior court judge's analysis that if petitioners unlawfully and intentionally killed Mr. Herbert, the malice could be presumed regardless of their motive.

The use of the term "unlawful" in defining a criminal homicide is generally to distinguish a criminal homicide from those homicides which society has determined to be "justifiable" or "excusable." Euthanasia, of course, is neither justifiable nor excusable in California.

In California, homicide is excusable, inter alia, "when committed by *accident* and *misfortune,* . . . in doing any . . . lawful act by lawful means, with usual and ordinary caution, and without any unlawful intent." Since petitioners conduct, whether lawful or unlawful, was intentional, if it resulted in the shortening of Mr. Herbert's life, it was not a matter of *accident* and *misfortune.*

Since "justifiable" homicide, by a person other than a peace officer, in California is limited essentially to cases of self-defense and defense of others, that concept has no application here.

Obviously the above mentioned concepts evolved and were codified at a time well prior to the development of the modern medical technology which is involved here, which technology has caused our society to rethink its concepts of what constitutes "life" and " death."

This gap between the statutory law and recent medical developments has resulted in the instant prosecution and its attendant legal dispute. That dispute in order to be resolved within the framework of existing criminal law must be narrowed to a determination of whether petitioners' conduct was unlawful. That determination, as indicated above, must be made on the basis of principles other than those limited ones set forth in Penal Code sections 195 and 197.

The California Legislature has dealt partially with some of the problems that have arisen as a result of modern developments.

Historically, death has been defined in terms of cessation of heart and respiratory function. . . . Health and Safety Code section 7180 (a)(2)[1] now provides for an alternative definition in terms of irreversible cessation of all brain function.

This is a clear recognition of the fact that the real seat of "life" is brain function rather than mere metabolic processes which result from respiration and circulation.

Of course it is conceded by all that at the time petitioners terminated further treatment, Mr. Herbert was not "dead" by either statutory or historical standards since there was still some minimal brain activity. If Mr. Herbert had in fact been "brain dead," this prosecution could not have been instituted because one cannot be charged with killing another person who is already dead.

We deal here with the physician's responsibility in a case of a patient who, though not "brain dead," faces an indefinite vegetative existence without any of the higher cognitive brain functions. As one court stated the issue: "Now, however, we are on the threshold of new terrain—the penumbra where death begins but life, in some form, continues. We have been led to it by the medical miracles which now compel us to distinguish between 'death' as we have known it, and death in which the body lives in some fashion but the brain (or a significant part of it) does not."

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[1] Health and Safety Code section 7180 provides: "(a) An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards. (b) This article shall be applied and construed to effectuate its general purpose to make uniform the law with respect to the subject of this article states enacting it. (c) This article may be cited as the Uniform Detemination of Death Act."

Since the death with which we are here concerned occurred in 1981, former Health and Safety Code section 7180, adopted in 1974, was the statute then in effect. That statute provided in part: "A person shall be pronounced dead if it is determined by a physician that the person has suffered a total and irreversible cessation of brain function." For present purposes any distinctions between the current and former statutes are immaterial.

Because of the current gap between technology and law, physicians and families of these unfortunate victims are called upon to make intensely painful and personal decisions regarding their care without clearly defined legal guidelines.

This case, arising as it does in the context of the criminal law, belies the belief expressed by many that such decisions would not likely be subjects of criminal prosecution. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment,* a report on the Ethical, Medical and Legal Issues in Treatment Decisions, March 1983, ch. 1, pp. 32-39 (hereinafter cited as President's Commission). To our knowledge, however, this case is the first instance in which the issue has been presented in the context of a criminal prosecution.

Of course, the only long-term solution to this problem is necessarily legislative in nature. It is that body which must address the moral, social, ethical, medical and legal issues raised by cases such as the one at bench. Manifestly, this court cannot attempt to rewrite the statutory definition of death or set forth guidelines covering all possible future cases. Due to legislative inaction in this area, however, we are forced to evaluate petitioners' conduct within the context of the woefully inadequate framework of the criminal law.

At this juncture we observe that California has adopted the Natural Death Act which permits an adult individual to execute, in advance, a directive for the withholding or withdrawing of life sustaining procedures in the event that he or she later suffers a terminal condition....

The superior court judge relied heavily on the fact that the deceased had not previously executed a written directive pursuant to Health and Safety Code section 7188 and he viewed the family's request as a nullity.

In adopting the Natural Death Act ... the Legislature has gone part-way, but only part-way, in dealing with this troublesome issue. The lack of generalized public awareness of the statutory scheme and the typically human characteristics of procrastination and reluctance to contemplate the need for such arrangements however makes this a tool which will all too often go unused by those who might desire it.

Furthermore, as commentators have noted, the Act functions as intended for only a very limited number of patients. If the directive is executed by a person *prior* to his having been diagnosed as terminally ill, it is not binding on the physician....In addition, the procedural requirements (especially the requirement in Health and Safety Code section 7191 (d) that the patient wait 14 days after diagnosis of terminal illness) are so cumbersome that it is unlikely that any but a small number of highly educated and motivated patients will be able to effectuate their desires....

Practical utility aside, the Act, according to its own terms, does not purport to be the exclusive means by which such decisions can be made.

Health and Safety Code section 7193 provides:

> "Nothing in this chapter shall impair or supersede any legal right or legal responsibility which any person may have to effect the withholding or withdrawal of life-sustaining procedures in any lawful manner. In such respect the provisions of this chapter are cumulative."

We thus turn to an analysis of the superior court's determination that petitioner's conduct was "unlawful" as a matter of law.

In this state a clearly recognized legal right to control one's own medical treatment pre-dated the Natural Death Act. A long line of cases, approved by the Supreme Court in *Cobbs v. Grant* (1972) 8 Cal. 3d 229, have held that where a doctor performs treatment in the absence of an informed consent, there is an actionable battery. The obvious corollary to this principle is that a competent adult patient has the legal right to refuse medical treatment.

It is clear from the legislative findings and declaration provided in Health and Safety Code section 7186, that the Legislature recognized such a right to control one's medical treatment, especially in circumstances such as presented here.

"The Legislature finds that adult persons have the fundamental right to control the decisions relating to the rendering of their own medical care, including the decision to have life-sustaining procedures withheld or withdrawn in instances of a terminal condition.

"The Legislature further finds that modern medical technology has made possible the artificial prolongation of human life beyond natural limits.

"The Legislature further finds that, in the interest of protecting individual autonomy, such prolongation of life for persons with a terminal condition may cause loss of patient dignity and unnecessary pain and suffering, while providing nothing medically necessary or beneficial to the patient."

Therefore we conclude that Health and Safety Code section 7188 does not represent the exclusive basis for terminating life-support equipment in this state. Nor is a diagnosis of "brain dead" a condition precedent to the cessation of such treatment.

As a predicate to our analysis of whether the petitioners' conduct amounted to an "unlawful killing," we conclude that the cessation of "heroic" life support measures is not an affirmative act but rather a withdrawal or omission of further treatment.

Even though these life support devices are, to a degree "self-propelled," each pulsation of the respirator or each drop of fluid introduced into the patient's body by intravenous feeding devices is comparable to a manually administered injection or item of medication. Hence "disconnecting" of the mechanical devices is comparable to withholding the manually administered injection or medication.

Further we view the use of an intravenous administration of nourishment and fluid, under the circumstances, as being the same as the use of the respirator or other form of life support equipment.

The prosecution would have us draw a distinction between the use of mechanical breathing devices such as respirators and mechanical feeding devices such as intravenous tubes. The distinction urged seems to be based more on the emotional symbolism of providing food and water to those incapable of providing for themselves rather than on any rational difference in cases such as the one at bench.

Medical nutrition and hydration may not always provide net benefits to patients. Medical procedures to provide nutrition and hydration are more similar to other medical procedures than to typical human ways of providing nutrition and hydration. Their benefits and burdens ought to be evaluated in the same manner as any other medical procedure.

The authority cited by the People for the holding that a murder charge may be supported by the failure to feed an infant is easily distinguishable. The parent in that case had a clear duty to feed an otherwise healthy child. As we will discuss, *infra*, the duty of a physician under the circumstances of the case at bench is markedly different.

In the final analysis, since we view petitioners' conduct as that of omission rather than affirmative action, the resolution of this case turns on whether petitioners had a duty to continue to provide life sustaining treatment.

There is no criminal liability for failure to act unless there is a legal duty to act. Thus the critical issue becomes one of determining the duties owed by a physician to a patient who has been reliably diagnosed as in a comatose state from which any meaningful recovery of cognitive brain function is exceedingly unlikely.

"A physician, surgeon or dentist must exercise that degree of skill or care *usual* in the profession in the place in which he practices; i.e., the standard is set by doctors of good standing practicing in that locality. [Citations.] It follows that 'Mere error of judgment, in the absence of a want of reasonable care and skill in the application of his medical learning to the case presented, will not render a doctor responsible for untoward consequences in the treatment of his patient. . .' [Citation.]"

In examining this issue we must keep in mind that the life-sustaining technology involved in this case is not traditional treatment in that it is not being used to directly cure or even address the pathological condition. It merely sustains biological functions in order to gain time to permit other processes to address the pathology.

The question presented by this modern technology is, once undertaken, at what point does it cease to perform its intended function and who should have the authority to decide that any further prolongation of the dying process is of no benefit to either the patient or his family?

A physician has no duty to continue treatment, once it has proved to be ineffective. Although there may be a duty to provide life-sustaining machinery in the *immediate* aftermath of a cardio-respiratory arrest, there is no duty to continue its use once it has become futile in the opinion of qualified medical personnel.

"A physician is authorized under the standards of medical practice to discontinue a form of therapy which in his medical judgment is useless. . . . If the treating physicians have determined that continued use of a respirator is useless, then they may decide to discontinue it without fear of civil or criminal liability. By useless is meant that the continued use of the therapy cannot and does not improve the prognosis for recovery."

Of course, the difficult determinations that must be made under these principles is the point at which further treatment will be of no reasonable benefit to the patient, who should have the power to make the decision and who should have the authority to direct termination of treatment.

No precise guidelines as to when or how these decisions should be made can be provided by this court since this determination is essentially a medical one to be made at a time and on the basis of facts which will be unique to each case. If specific procedural rules are to be adopted in this area in order to protect the public interest, they must necessarily come from that body most suited for the collection of data and the reaching of a consensus—the Legislature. However, we would be derelict in our duties if we did not provide some general guidelines for future conduct in the absence of such legislation.

"[T]here must be a way to free physicians, in the pursuit of their healing vocation, from possible contamination by self-interest or self-protection concerns which would inhibit their independent medical judgments for the well-being of their dying patients. We would hope that this opinion might be serviceable to some degree in ameliorating the professional problems under discussion."

Several authorities have discussed the issue of which life-sustaining procedures must be used and for how long their use must be maintained in terms of "ordinary" and "extraordinary" means of treatment. The use of these terms begs the question. A more rational approach involves the determination of whether the proposed treatment is proportionate or disproportionate in terms of the benefits to be gained versus the burdens caused.

Under this approach, proportionate treatment is that which, in the view of the patient, has at least a reasonable chance of providing benefits to the patient, which benefits outweigh the burdens attendant to the treatment. Thus, even if a proposed course of treatment might be extremely painful or intrusive, it would still be proportionate treatment if the prognosis was for complete cure or significant improvement in the patient's condition. On the other hand, a treatment course which is only minimally painful or intrusive may nonetheless be considered disproportionate to the potential benefits if the prognosis is virtually hopeless for any significant improvement in condition.

Several authorities have struggled with this issue and some consensus has been reached on the theory if not the terminology.

"[O]ne would have to think that the use of the same respirator or like support could be considered 'ordinary' in the context of the possibly curable patient but 'extraordinary' in the context of the forced sustaining by cardiorespiratory processes of an irreversibly doomed patient." *(Matter of Quinlan, supra, at p. 668.)*

Thus, the determination as to whether the burdens of treatment are worth enduring for any individual patient depends on facts unique to each case, namely, how long the treatment is likely to extend life and under what conditions. "[S]o long as a mere biological existence is not considered the *only* value, patients may want to take the nature of what additional life into account as well." (President's Commission, ch. 2, at p. 88.)

Of course the patient's interests and desires are the key ingredients of the decision making process. When dealing with patients for whom the possibility of full recovery is virtually non-existent, and who are incapable of expressing their desires, there is also something of a consensus on the standard to be applied.

"[T]he focal point of decision should be the prognosis as to the reasonable possibility of return to cognitive and sapient life, as distinguished from the forced continuance of that biological vegetative existence . . . ." *(Matter of Quinlan, supra, at p. 669.)*

" 'Prolongation of life,' . . . does not mean a mere suspension of the act of dying, but contemplates, at the very least, a remission of symptoms enabling a return towards a normal, functioning, integrated existence." *(Matter of Dinnerstein (1978) 380 N.E. 2d 134, at p. 138.)*

The evidence presented at the preliminary hearing supports the conclusion that petitioners reasonably concluded that Mr. Herbert had virtually no chance of recovering his cognitive or motor functions. The most optimistic prognosis provided by any of the testifying experts was that the patient had an excellent chance of "recovery." However, recovery was defined in terms of a spectrum running from a persistent vegetative state to full recovery. A persistent vegetative state was described as that state in which the patient would have no contact with the environment but parts of the brain would continue to live. The doctor who was of course approaching the case after the fact and from a hindsight view, was unable to predict where on this continuum Mr. Herbert was likely to end up. Several studies on which the expert relied, however, indicated that the chances for unimpaired or full recovery were miniscule. The results of these studies coincided with the diagnoses of the physicians who had actually examined and dealt with the patient before his demise.

Given the general standards for determining when there is a duty to provide medical treatment of debatable value, the question still remains as to who should make these vital decisions. Clearly, the medical diagnoses and prognoses must be determined by the treating and consulting physicians under the generally accepted standards of medical practice in the community and, whenever possible, the patient himself should then be the ultimate decision-maker.

When the patient, however, is incapable of deciding for himself, because of his medical condition or for other reasons, there is no clear authority on the issue of who and under what procedure is to make the final decision.

It seems clear, in the instant case, that if the family had insisted on continued treatment, petitioners would have acceded to that request. The family's decision to the contrary was, as noted, ignored by the superior court as being a legal nullity.

In support of that conclusion the People argue that only duly appointed legal guardians have the authority to act on behalf of another. While guardianship proceedings might be used in this context, we are not aware of any authority *requiring* such procedure. In the case at bench, petitioners consulted with and relied on the decisions of the immediate family, which included the patient's wife and several of his children. No formal guardianship proceedings were instituted.

In the absence of legislation requiring such legal proceedings, we cannot say that failure to institute such proceedings made petitioners' conduct unlawful. Whether such proceedings are to be required in the future is again a question for the Legislature to decide.

The authorities are in agreement that any surrogate, court appointed or otherwise, ought to be guided in his or her decisions first by his knowledge of the patient's own desires and feelings, to the extent that they were expressed before the patient became incompetent. (President's Commission, ch. 4, p. 132; *Superintendent of Belchertown v. Saikewicz, supra,* p. 431)

If it is not possible to ascertain the choice the patient would have made, the surrogate ought to be guided in his decision by the patient's best interests. Under this standard, such factors as the relief of suffering, the preservation or restoration of functioning and the quality as well as the extent of life sustained may be considered. Finally, since most people are concerned about the well-being of their loved ones, the surrogate may take into account the impact of the decision on those people closest to the patient. (President's Commission, ch. 4, pp. 134-35.)

There was evidence that Mr. Herbert had, prior to his incapacitation, expressed to his wife his feeling that he would not want to be kept alive by machines or "become another Karen Ann Quinlan." The family made its decision together (the directive to the hospital was signed by the wife and eight of his children) after consultation with the doctors.[2]

Under the circumstances of this case, the wife was the proper person to act as a surrogate for the patient with the authority to decide issues regarding further treatment, and would have so qualified had judicial approval been sought. There is no evidence that there was any disagreement among the wife and children. Nor was there any evidence that they were motivated in their decision by anything other than love and concern for the dignity of their husband and father.

Furthermore, in the absence of legislative guidance, we find no legal requirement that prior judicial approval is necessary before any decision to withdraw treatment can be made.

Although there is not complete agreement among the courts that have addressed the issue in the civil context, we agree with those which have held that requiring judicial intervention in all cases is unnecessary and may be unwise. *(Matter of Quinlan, supra; Matter of Storar* (1981) 420 N.E. 2d 64, U.S. cert. den., 454 U.S. 858.*)*

The *Quinlan* court stated at page 669: "We consider that a practice of applying to a court to confirm such decisions would generally be inappropriate, not only because that would be a gratuitous encroachment upon the medical profession's field of competence, but because it would be impossibly cumbersome. . . . This is not to say that in the case of an otherwise justiciable controversy access to the courts would be foreclosed; we speak rather of a general practice and procedure."

In summary we conclude that the petitioners' omission to continue treatment under the circumstances, though intentional and with knowledge that the patient would die, was not an unlawful failure to perform a legal duty. In view of our decision on that issue, it becomes unnecessary to deal with the further issue of whether petitioners' conduct was in fact the proximate cause of Mr. Herbert's ultimate death.

The evidence amply supports the magistrate's conclusion. The superior court erred in determining that as a matter of law the evidence required the magistrate to hold petitioners to answer.

Let a peremptory writ of prohibition issue to restrain the Superior Court of Los Angeles County from taking any further action in this matter other than to vacate its order reinstating the complaint and enter a new and different order denying the People's motion under Penal Code section 871.5.

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[2] The people urge that petitioners were obligated to consult Mr. Herbert's sister-in-law rather than his wife and children for this most important decision. Despite the fact that Mr. Herbert apparently entered the name of his sister-in-law on a hospital form (the purpose of which was unclear from the evidence), his wife and children were the most obviously appropriate surrogates in this case. They were the people who would be most affected by the decision and were in the best position to know Mr. Herbert's own feelings and desire. In addition, there was clear evidence that they were concerned for his comfort and welfare and some or all of them were present at the hospital nearly around the clock.

Malpractice Causes MDs' Depression

Medical malpractice suits and the fear of them cause 57% of physicians to be either depressed or pervasively angry, according to a report by Sara C. Charles, MD, a psychiatrist at the University of Illinois in Chicago. Other findings of the study of 346 members of the Chicago Medical Society (56% of whom reported having been sued) are:

- •67.6% of sued doctors and 59.6% of nonsued doctors order more diagnostic tests than their clinical judgments deemed necessary.
- •42.8% of sued and 32.6% of nonsued doctors stopped performing high-risk procedures.
- •49% of sued and 29.5% of nonsued doctors would stop seeing patients who were more likely to sue for malpractice.
- •74.5% of sued and 78.6% of nonsued doctors keep more meticulous records.
- •30.5% of sued and 39.3% of nonsued doctors study medical journals more frequently.
- •27.3% of sued and 31.4% of nonsued doctors attend more certified continuing medical education courses.
- •Of those who had been sued, about 10% had gone to trial and less than 2% lost their cases to patients. Most felt strongly that settling a suit out of court is tantamount to an admission of guilt.

—*Physician's Management,* July, 1985

DRUG INFORMATION UPDATE: HARTFORD HOSPITAL

Nalbuphine

RICHARD GANNON, PHARM.D.

Nalbuphine (Nubain®) is a narcotic agonist-antagonist which does not have the adverse CNS and hemodynamic side effects of pentazocine (Talwin®) and does not cause the hypotension or biliary tract spasm associated with morphine administration.

Pharmacology and Pharmacokinetics

It is postulated that there are three different narcotic receptors.[1] The mu receptor mediates analgesia, euphoria, respiratory depression, sedation and miosis. The kappa receptor mediates analgesia, sedation, amnesia, and miosis. The lambda receptor mediates dysphoric reactions, psychotomimetic actions, mydriasis, and respiratory stimulation. The following table details the activity of morphine, nalbuphine, pentazocine and naloxone at these receptors:

Narcotic Receptors

	Mu	*Kappa*	*Lambda*
Morphine	Agonist	Agonist (weak)	?
Nalbuphine	Antagonist	Agonist	Agonist (weak)
Pentazocine	Antagonist	Agonist	Agonist
Naloxone	Antagonist	Antagonist	Antagonist

Nalbuphine is equipotent to morphine with 10 mg of parenteral nalbuphine achieving the same degree of analgesia as 10 mg of parenteral morphine.[2-3] The half-life of nalbuphine is approximately 3-5 hours. Nalbuphine is metabolized primarily by the hepatic route with 7% of a parenteral dose eliminated in the urine as unchanged drug.[3]

Clinical Studies

In two separate studies, volunteers were given 0.15 mg/kg of IV nalbuphine or morphine every 30-45 minutes up to a total of 0.6 mg/kg. After a total of 0.3 mg/kg of nalbuphine there were no further decreases in minute ventilation or increase in PCO_2 while with morphine there were further significant changes with each dose increment.[2,5] Therefore, nalbuphine appears to have lower respiratory depressant potential than morphine at doses of >0.3 mg/kg.

When given as single 0.15 mg/kg doses both morphine and nalbuphine significantly increase the threshold and tolerance for experimental pain. Morphine progressively increased pain tolerance from 30% above control with the first dose to 107% above control after a cumulative dose of 0.6 mg/kg. Nalbuphine produced a 40% increase in pain tolerance with the first dose of 0.15 mg/kg but additional increments of nalbuphine did not result in significantly greater analgesia.[2] Nalbuphine therefore, appears to be less potent than morphine at doses >0.15 mg/kg.

Patients with coronary artery disease and valvular heart disease have been given large doses of nalbuphine (0.5 – 3 mg/kg)IV without any significant hemodynamic changes occurring.[6] Comparable doses of pentazocine (Talwin®) and butorphanol (Stadol®) increase pulmonary artery and left ventricular pressures as well as systemic vascular resistance.[1]

Epidural (10 mg) and intrathecal (0.4 mg) nalbuphine have produced analgesia and side effects similar to that of morphine given by the same route and in the same dose.[9]

Patients undergoing cesarean section have received 0.2 mg/IV nalbuphine prior to delivery. Nalbuphine serum levels were higher in the neonate than the mother shortly after delivery. Neonates were rated for respiratory effort, reflex irritability, muscle tone, heart rate, and color. All neonates were rated close to normal with APGAR scores of 6.6 at 1 minute and 8.5 at 5 minutes.[10]

Adverse Effects

The same degree of sedation has been seen with nalbuphine and morphine when cumulative IV doses up to 0.6 mg/kg have been given.[2-3]

Respiratory depression is similar between nalbuphine and morphine with single doses. However, with cumulative dosing there appears to be a ceiling effect with nalbuphine.[2-3] This ceiling effect may also apply to nalbuphine's analgesic activity with sedation and amnesia replacing analgesia.[2,4]

RICHARD GANNON, PHARM.D., Clinical Pharmacist in Medicine, Hartford Hospital, Hartford, CT; Assistant Clinical Professor, University of Connecticut, School of Pharmacy, Storrs, CT.

This new series on Drug Information Updates from the Hartford Hospital are supplied by Charles H. Nightingale, PH.D., Director of Pharmacy Services, Hartford Hospital.

Editors: Moses Sing Sum Chow, PHARM.D. and Robert A. Quercia, M.S., R.PH.

Psychotomimetic effects (hallucinations, delusions, dysphoria, feelings of unreality) occur infrequently with nalbuphine when compared to pentazocine. In a double blind crossover study by House,[3] 52% of patients who received 60 mg of IM pentazocine had psychotomimetic reactions whereas only 7% had these effects from 10-20 mg of IM nalbuphine. Total daily doses of nalbuphine greater than 2 mg/kg are associated with an increased incidence of psychotomimetic effects.

Narcotics are known for their ability to increase common bile duct pressure. Nalbuphine, 0.15-1.25 mg/kg IV, has been given to patients with only slight (non-significant) increases in biliary tract pressure occurring when compared to baseline pressures.[7-8]

Other adverse effects of nalbuphine include dizziness, vertigo, dry mouth, headache, and approximately 50% of patients complain of transient burning at the IV injection site.

Because of its antagonist property, nalbuphine may precipitate withdrawal symptoms in patients addicted to "street" narcotics or in patients receiving chronic narcotic therapy. The dependence liability is similar to that of pentazocine. Naloxone (0.4-0.8 mg) reverses the sedation and respiratory depression from nalbuphine. Nalbuphine does not cause histamine release as other narcotics do. (Personal Communication, Endo Pharmaceuticals).

Dosage and Administration

The average dose in an adult is 0.1-0.2 mg/kg given SC, IM, or IV every 3-6 hours as needed. The onset, peak, and duration of action are summarized below:

Route of Administration

	SC/IM	*IV*
Onset Activity	15 min.	2-3 min.
Peak Activity	1 hr.	30 min.
Duration of Action	3-6 hr.	2-6 hr.

Nalbuphine should be administered by IV push (may be diluted with D5W or NS) over one minute when used intravenously. Nalbuphine is not a controlled substance, therefore its storage and use is not subject to the regulations regarding the storage and use of controlled substances.

It is available as 10 mg/ml and 20 mg/ml in 1 ml and 2 ml amps or 10 ml vials. The injection contains methylparaben, propylparaben and sodium metabisulfite as preservatives.

Cost Comparison

Equivalent Dose (Injection)	*Pharmacy Cost*
Nalbuphine 10 mg	$1.50
Pentazocine 60 mg	1.60
Morphine Sulfate 10 mg	.20
Meperidine 100 mg	.15

Summary and Recommendations

Nalbuphine causes analgesia equivalent to morphine with single IV doses of 0.15 mg/kg but at higher doses of nalbuphine, there appears to be a ceiling effect on both analgesia and respiratory depression. In view of its potential for a ceiling on analgesia and much higher cost than morphine, nalbuphine should not be used routinely in all patients. Nalbuphine is a potentially useful agent in the following clinical situations:

1. Patients with hypotension requiring sedation or analgesia
2. Patients with acute myocardial infarction requiring analgesia when morphine has caused hypotension
3. Patients in whom potential elevations in biliary tract pressures are to be avoided

Richard Gannon, Pharm.D.

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Current Medicolegal Issues

AMA – THE CITATION

California Law Limiting Damages In Malpractice Suits Is Constitutional

A provision in the California Medical Injury Compensation Reform Act that limits the amount of damages for non-economic losses to $250,000 was constitutional, the California Supreme Court ruled.

A 34-year-old patient employed by the California State Legislature felt a brief pain in his chest as he was riding his bicycle to work on February 21, 1976. He noticed a similar brief pain the next day while he was jogging, and again three days later while walking after lunch. He made an appointment with his regular physician, who was employed by an HMO. He was examined by a nurse-practitioner, who consulted with her physician consultant. When she returned to the room, she advised him that they believed his pain was due to muscle spasm. The physician prescribed Valium and the patient went home.

That night he awoke with severe chest pains. His wife took him to the HMO emergency room, where he was examined by a physician. The physician ordered a chest X-ray and, on the basis of his examination and the X-ray results, the physician concluded that the patient was experiencing muscle spasms. He gave him an injection of Demerol and a prescription for codein-containing medication.

The patient went home, but continued to experience intermittent chest pain. About noon the same day, the pain became more severe and constant and he returned to the HMO emergency room. Another physician initially believed that his problem was of muscular origin, but he directed that an EKG be performed. The EKG showed that the patient was suffering from an acute myocardial infarction. He was then transferred to the cardiac care unit. He returned to his job part-time about seven months later and full-time in September 1977. At that time he had been permitted to return to virtually all of his prior recreational activities.

In a malpractice action against the HMO, the patient's expert witness testified that the HMO should have conducted an EKG during the patient's first two visits to his physician and to the emergency room. He testified that if an EKG had been ordered at those times, it could have revealed the patient's imminent heart attack and treatment could have been administered that might have prevented or minimized the attack. He testified that a large portion of the patient's heart muscle had died, reducing his life expectancy by about one-half.

The HMO's expert witnesses indicated that an EKG would not have shown that a heart attack was imminent and that because of the severe disease in the patient's coronary arteries, the heart attack could not have been prevented even if it had been known that it was about to occur.

A jury found in favor of the patient and awarded $24,733 for lost wages, $63,000 for future medical expenses, $700,000 for wages lost in the future as a result of the reduction in his life expectancy, $500,000 in non-economic damages for pain, suffering, physical impairment and other intangible damages.

A trial court reduced the non-economic damages to $250,000 pursuant to the Medical Injury Compensation Reform Act. The court reduced the award for past lost wages by deducting the amount he had already received in disability payments and ordered the HMO to pay the first $63,000 of any future medical expenses not covered by the patient's medical insurance. The trial court also declined to order the award for future lost wages and economic damages to be paid periodically.

Affirming the decision, the California Supreme Court upheld the constitutionality of the limitation of non-economic damages in medical malpractice cases to $250,000. The provision was rationally related to the state objective of reducing the costs of malpractice defendants and their insurance companies and did not violate due process. It did not violate equal protection rights on the ground that it discriminated between medical malpractice victims and other tort victims, the court said.

Further the court said that an additional provision of the Act that modified the collateral source rule was not unconstitutional. Under the collateral source rule, payments by third parties such as medical insurance or disability benefits could not be considered by a jury in calculating a patient's damages. Under the Act, payments received from collateral sources could be considered in calculating damages.—*Fein v. Permanente Medical Group,* 695 P.2d 665, 211 Cal. Rptr. 368 (Cal. Sup. Ct., Feb. 28, 1985)

Psychiatrist Who Treated Hinckley Not Liable

A federal trial court did not err in finding that a psychiatrist had no legal duty to protect the persons injured by his former patient in an attempted assassination of President Reagan, a federal appellate court for Colorado ruled.

Three victims who were shot and seriously injured in the assassination attempt sued the psychiatrist for alleged negligence in examining, diagnosing, and treating John Hinckley, Jr., and in failing to warn others of the danger

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THE CITATION is a newsletter on medicolegal issues prepared by the Office of The General Counsel of the American Medical Association.

posed by him. The psychiatrist treated Hinckley from October 1980 to March 1981. The assassination attempt was on March 30, 1981.

A trial court found that the psychiatrist owed no duty to the victims in the absence of allegations that the patient had conveyed specific threats against the victims to him. The court found that there was no relationship between the psychiatrist and the victims that created any legal obligation from the psychiatrist to the victims.

On appeal, the court agreed with the lower court that the victims' injuries were not foreseeable and that the victims fell outside the scope of the psychiatrist's duty. The court held that the trial court's conclusions, interpreting applicable Colorado law, were not clearly erroneous under the circumstances of the case. —*Brady v. Hopper,* 751 F.2d 329 (C.A.10, Colo., Dec. 27, 1984)

Editor's Note: A prior decision in this case was reported in THE CITATION, Vol. 48, No. 9, p. 98.

Summary Suspension of MD's Staff Privileges Vacated

The summary suspension of an anesthesiologist's staff privileges should be vacated, a New York appellate court ruled.

The anesthesiologist's privileges were suspended after a meeting of the hospital's Joint Conference Committee. The minutes of the meeting revealed that there was some discussion about personality clashes between the anesthesiologist and other staff members and some surgeons did not want to work with him as an anesthesiologist. It was suggested that the anesthesiologist's mood swings and agitation were signs of mental impairment. Expressing the desire to protect both the patients and the hospital pending a state investigation, the Committee voted to invoke the hospital's bylaws authorizing summary suspension of his privileges. The anesthesiologist was advised that the actions had been taken in the belief that he may have a mental disability or impairment that manifested itself in periodic defects in the delivery of professional care to patients.

The Medical Board said that the summary suspension should be nullified by the Board of Trustees. At a second meeting the Medical Board decided to recommend to the Board of Trustees that the suspension be revoked if a psychiatric evaluation failed to establish any evidence of a mental disability. A psychiatrist chosen by the hospital interviewed and tested the anesthesiologist and concluded that there was no evidence of any psychiatric illness to preclude his functioning as an anesthesiologist. Nevertheless, the suspension was not revoked.

In an action challenging suspension of his privileges, a trial court entered a judgment vacating the suspension. The appellate court affirmed the decision. The hospital had violated its own bylaws by suspending his privileges at an informal disciplinary meeting, without written notice of any adverse decision by the Medical Board or Board of Trustees. The anesthesiologist did not have to resort to an administrative review before bringing the lawsuit, the appellate court said. Administrative review was not available to the anesthesiologist, since the Joint Conference Committee had stated the reasons for suspending him and the stated reasons did not relate to institutional concerns, the court added.—*Murphy v. St. Agnes Hospital,* 484 N.Y.S.2d 40 (N.Y. Sup. Ct., App. Div., Jan. 14, 1985)

Hospital Acted Properly in Placing Physician On Probation

A hospital was entitled to summary judgment in an action by a physician who claimed that its actions in placing him on probation and removing him from the teaching staff and emergency room call list violated due process, a federal trial court in Texas ruled.

The physician was a board-certified orthopedic surgeon. He had been a member of the medical staff of the hospital since 1977. In late 1982, the Membership, Ethics and Credentials Committee at the hospital held a special meeting to discuss certain incidents concerning the physician. He attended the meeting. As a result, the Committee requested the Executive Committee to take corrective action against the physician. The Executive Committee met to consider the request, with the physician in attendance. After reviewing the incident and grievance reports and hearing the physician's response, the Executive Committee placed him on probation for one year.

Without any advance notice, the resident trainer in orthopedics removed the physician from the teaching staff for orthopedic residents. A few months later, the Emergency Room Committee removed him from the emergency room call list for a six-month period for violation of express rule against the insertion of pins in the emergency room. The suspension ended after six months and he was reinstated on the call list. He was given no advance notice of the Emergency Room Committee's action.

In an action against the hospital, the physician claimed that its actions deprived him of a property or liberty interest in his continued status as a non-probationary physician and that this deprivation was without due process. He also claimed that the hospital failed to follow its own policies and procedures in placing him on probation. The hospital argued that the physician's positions on the teaching staff and the emergency room call list were both voluntary and uncompensated and that he had no recognizable property or liberty interests in those positions.

Granting summary judgment in favor of the hospital, the court said that the hospital's action in placing the physician on probation did not deprive him of any recognizable property or liberty interest. There was no evidence of any understanding that the hospital would remove physicians from the teaching staff and the call list only for cause. The court said that the teaching staff and emergency room call list privileges were not staff privileges. Staff privileges were those that were directly related to the practice of the medical profession. Teaching staff and emergency room call privileges were independent of the physician's privileges to practice medicine at the hospital. —*Elbaor v. Grand Prairie Hospital Authority,* 599 F. Supp. 1111 (D.C., Tex., Oct. 22, 1984)

Discharged Nurse Sues For Breach Of Contract

A hospital was not entitled to summary judgment in a breach of contract action against it by an employee whom it had fired, the Arizona Supreme Court ruled.

The employee was hired in 1972, as the hospital's operating room supervisor. In 1978, she became the director of nursing. On October 1, 1979, she requested a transfer to her former position in the operating room. She had submitted a written request to the director of the hospital. Because of a change in ownership of the hospital, a new chief executive was appointed. He met with the nurse shortly after his arrival and indicated that he would act on her transfer request shortly.

At a subsequent meeting, he expressed his opinion that it was inadvisable for someone who had been in a managerial position to take a position subordinate to his or her earlier one. Despite her eventual withdrawal of the transfer request, the nurse was fired by the new chief executive on November 14, 1979. Her personnel record shows, "insubordination" as the reason for her discharge. However, the chief executive testified that she was terminated because of her request to transfer to a subordinate position that was not actually open.

She was paid for her hours worked and for her accrued vacation and holiday time and received three weeks' severance pay. She requested a "grievance hearing" as provided in the hospital's personnel policy manual, but was denied it. She filed suit against the hospital and the chief executive, alleging breach of contract and defamation. A trial court entered summary judgment against her on the grounds that her employment relationship was terminable at will and that no defamatory statements about her had been made. An appellate court reversed the summary judgment and remanded for further proceedings.

On appeal, the Arizona Supreme Court said that representations in a personnel manual can become terms of an employment contract and can limit the employer's ability to discharge its employees. Whether a personnel manual modified a particular employment at will relationship is a question of fact. Evidence relevant to this decision includes the language used in the personnel manual as well as the employer's course of conduct and oral statements regarding it. The court said that once the hospital issued a policy, it had to follow it.

The court noted that the language used in the hospital's handbook was quite similar to the language used in another employer's handbook in which a requirement of cause for termination was found to exist. The court remanded the decision to the trial court for a determination whether the policy manual became part of her employment contract and whether the hospital breached that contract. —*Leikvold v. Valley View Community Hospital,* 688 P.2d 170 (Ariz. Sup. Ct., April 25, 1984)

Court Reverses Jury Verdict For Physician In Hospital Staff Privileges Case

A trial court erred in awarding a surgeon $400,000 in an action against a hospital for violation of its bylaws in dealing with his request for privileges, an Indiana appellate court ruled.

The physician had active staff privileges at the hospital in 1980, when he requested privileges in endoscopic procedures. He had received continuing education credits for short courses in fiberoptic bronchoscopy and other endoscopic procedures. In June 1980, he filed an application for reappointment to the hospital's active staff for the two-year period July 1, 1980 to June 30, 1982. The application also contained a request for various privileges including some endoscopic procedures. The hospital ultimately granted him all of the requested privileges. However, it required him to be supervised in a small number of the procedures he requested—procedures which he had not performed in a number of years or which he performed very rarely.

In an action against the hospital, the physician claimed that it had violated its bylaws in the manner in which it ultimately granted him the procedures he requested with supervision. A trial court entered a judgment in his favor in the amount of $400,000 after a jury verdict in favor of the physician.

Reversing the decision, the appellate court said that the hospital staff bylaws could constitute a contract between the hospital and its medical staff. The court said that if any breaches of the bylaws did occur, they were merely technical in nature. The determination to grant the surgeon privileges with a small number of those privileges under supervision was made only after an extensive review procedure had been undertaken. The hospital had substantially complied with the essential portions of the bylaws, the court said.

Even if the surgeon was damaged as a consequence of the alleged violation of the bylaws, he had failed to show that he ever lost a patient referral or suffered any other damages from that action. One concurring judge stated that there was not one demonstrable incident that indicated that he lost one patient or one dollar because of the requirement for supervision of the nine procedures. In addition, he was on the staff with full privileges at another hospital in the same city. —*Terre Haute Regional Hospital, Inc. v. El-Issa,* 470 N.E.2d 1371 (Ind. Ct. of App., Nov. 26, 1984)

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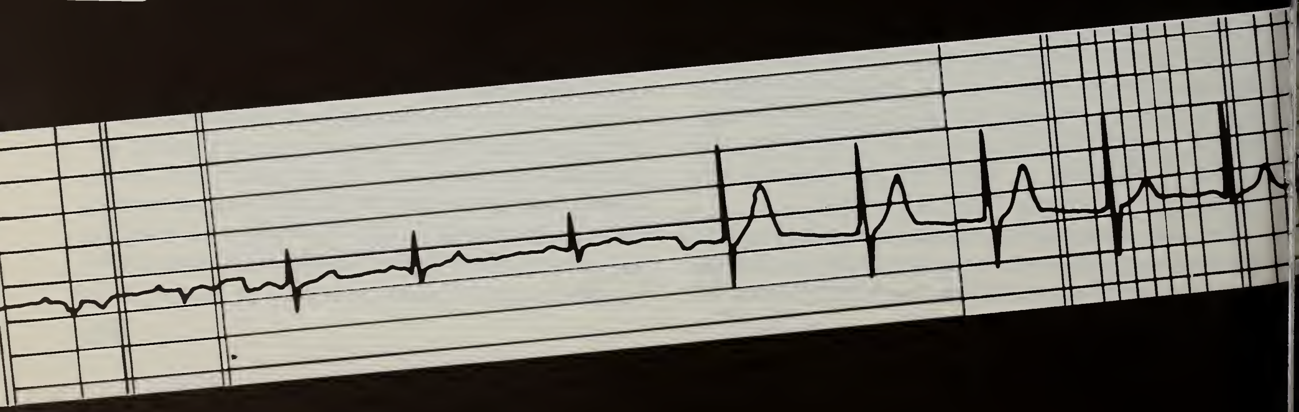

Recommendations for Protection Against Viral Hepatitis

CENTERS FOR DISEASE CONTROL

The following statement updates all previous recommendations on use of immune globulins for protection against viral hepatitis (*MMWR* 1981; 20:423-435) and use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis of hepatitis B (*MMWR* 1982; 31:317-328 and 1984; 33:285-290).

Introduction

The term "viral hepatitis" is commonly used for several clinically similar diseases that are etiologically and epidemiologically distinct.[1] Two of these, hepatitis A (formerly called infectious hepatitis) and hepatitis B (formerly called serum hepatitis) have been recognized as separate entities since the early 1940s and can be diagnosed using specific serologic tests. The third, currently known as non-A, non-B hepatitis, is probably caused by at least two different agents, and lacking specific diagnostic tests, remains a disease diagnosed by exclusion. It is an important form of acute viral hepatitis in adults and currently accounts for most posttransfusion hepatitis in the United States. An epidemic type of non-A, non-B hepatitis, which is probably spread by the fecal-oral route and is different from the types seen in the United States, has been described in parts of Asia and North Africa.[2]

A fourth type of hepatitis, δ-hepatitis, has recently been characterized as an infection dependent on hepatitis B virus. It may occur as a coinfection with acute hepatitis B infection or as superinfection of a hepatitis B carrier.[3]

Hepatitis Surveillance

Approximately 21,500 cases of hepatitis A, 24,300 cases of hepatitis B, 3,500 cases of non-A, non-B hepatitis, and 7,100 cases of hepatitis, type unspecified, were reported in the United States in 1983. Most cases of each type occur among young adults. Since reporting from many localities is incomplete, the actual number of hepatitis cases occurring annually is thought to be several times the reported number.

Immune Globulins

Immune globulins used in medical practice are sterile solutions of antibodies (immunoglobulins) from human plasma. They are prepared by cold ethanol fractionation of large plasma pools and contain 10% to 18% protein. In the United States, plasma is primarily obtained from professional donors. Only plasma shown to be free of hepatitis B surface antigen (HBsAg) is used to prepare immune globulins.

Immune globulin (IG) (formerly called immune serum globulin, ISG, or γ-globulin) produced in the United States contains antibodies against the hepatitis A virus (anti-HAV) and the hepatitis B surface antigen (anti-HBs). Tests of IG lots prepared since 1977 indicate that both types of antibody have uniformly been present. Hepatitis B immune globulin (HBIG) is an IG prepared from plasma containing high titers of anti-HBs.

Neither IG nor HBIG commercially available in the United States transmits hepatitis or other viral infections. There is no evidence that the causative agents of AIDS (human T-lymphotropic virus type III/lymphadenopathy-associated virus [HTLV-III/LAV]) has been transmitted by IG or HBIG.[4]

Serious adverse effects from immune globulins administered as recommended have been exceedingly rare. Standard immune globulins are prepared for intramuscular use and should not be given intravenously. Two preparations for intravenous use in immunodeficient and other selected patients have recently become available in the United States but are not recommended for hepatitis prophylaxis. Immune globulins are not contraindicated for pregnant women.

Hepatitis A

Hepatitis A is caused by the hepatitis A virus (HAV), a 27-nm ribonucleic acid (RNA) agent that is a member

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This is the first of a two-part series of the Immunization Practices Advisory Committee's recommendations on use of immune globulins for protection against viral hepatitis.

—*Morbidity and Mortality Weekly Report;* (Vol. 34, No. 22, 1985).

of the picornavirus family. The illness caused by HAV characteristically has an abrupt onset with fever, malaise, anorexia, nausea, abdominal discomfort, and jaundice. Severity is related to age. In children, most infections are asymptomatic, and illness is usually not accompanied by jaundice. Most infected adults become symptomatically ill with jaundice. Fatality among reported cases is infrequent (about 0.6%).

Hepatitis A is primarily transmitted by person-to-person contact, generally through fecal contamination. Transmission is facilitated by poor personal hygiene, poor sanitation, and intimate (intrahousehold or sexual) contact. Common-source epidemics from contaminated food and water also occur. Sharing utensils or cigarettes or kissing are not believed to transmit the infection.

The incubation period of hepatitis A is 15 to 50 days (average, 28 to 30 days). High concentrations of HAV (10^8 particles/g) are found in stools of infected persons. Fecal virus excretion reaches its highest concentration late in the incubation period and early in the prodromal phase of illness, and diminishes rapidly once jaundice appears. Greatest infectivity is during the two-week period immediately before the onset of jaundice. Viremia is of short duration; virus has not been found in urine or other body fluids. A chronic carrier state with HAV in blood or feces has not been demonstrated. Transmission of HAV by blood transfusion has occurred but is rare.

The diagnosis of acute hepatitis A is confirmed by finding IgM-class anti-HAV in serum samples collected during the acute or early convalescent phase of disease. IgG-class anti-HAV, which appears in the convalescent phase of disease and remains detectable in serum samples thereafter, apparently confers enduring protection against disease. Commercial tests are available to detect IgM anti-HAV and total anti-HAV in serum.

Although the incidence of hepatitis A in the United States has decreased over the last 15 years, it is still a common infection in older children and young adults. About 38% of reported hepatitis cases in this country are attributable to hepatitis A.

Recommendations for IG Prophylaxis of Hepatitis A

Numerous field studies conducted in the past four decades confirm that IG given before exposure or during the incubation period of hepatitis A is protective against clinical illness.[5-7] Its prophylactic value is greatest (80% to 90%) when given early in the incubation period and declines thereafter.[7]

Preexposure Prophylaxis

The major group for whom preexposure prophylaxis is recommended is international travelers. The risk of hepatitis A for US citizens traveling abroad varies with living conditions, incidence of hepatitis A infection in areas visited, and length of stay.[8-9] In general, persons traveling to developed areas of western Europe, Japan, and Australia are at no greater risk of infection than in the United States. In contrast, persons traveling to developing countries may be at significant risk of infection. In such areas, the best way to prevent hepatitis A and other enteric diseases is to avoid potentially contaminated water or food. Drinking water (or beverages with ice) of unknown purity and eating uncooked shellfish or uncooked fruits or vegetables that are not peeled (or prepared) by the traveler should be avoided.

Immune globulin is recommended for persons traveling to developing countries if they will be eating in settings of poor or uncertain sanitation (some restaurants or homes) or will be visiting extensively with local persons, especially young children, in settings with poor sanitary conditions. Persons who plan to reside in developing areas for long periods should receive IG regularly if they anticipate exposure as described above or will be living in rural areas with poor sanitation.

For such travelers, a single dose of IG of 0.02 mL/kg is recommended if travel is for less than two months. For prolonged travel, 0.06 mL/kg should be given every five months. For persons who require repeated IG prophylaxis, screening for total anti-HAV antibodies before travel may be useful to define susceptibility and eliminate unnecessary doses of IG in those who are immune.

Postexposure Prophylaxis

A serologic test for the diagnosis of acute hepatitis A is now widely available. Since only 38% of acute hepatitis cases in the United States result from hepatitis A, serologic confirmation of hepatitis A in the index case is recommended before treatment of contacts. Serologic screening of contacts for anti-HAV before giving IG is not recommended because screening is more costly than IG and would delay its administration.

Immune globulin should be given as soon as possible after exposure; giving IG more than two weeks after exposure is not indicated.

Specific recommendations for IG prophylaxis of hepatitis A depend on the nature of the HAV exposure:

1. Close personal contact. Immune globulin is recommended for all household and sexual contacts of persons with hepatitis A.
2. Day-care centers. Day-care facilities with children in diapers can be important settings for HAV transmission.[10-12] Immune globulin should be administered to all staff and attendees of day-care centers or homes if: (a) one or more hepatitis A cases are recognized among children or employees; or (b) cases are recognized in two or more households of center attendees. When an outbreak (hepatitis cases in three or more families) occurs, IG should also be considered for members of households whose diapered children attend. In centers not enrolling children in diapers, IG need only be given to classroom contacts of an index case.
3. Schools. Contact at elementary and secondary schools is usually not an important means of transmitting hepatitis A. Routine administration of IG is not indicated for pupils and teachers in contact with a pa-

tient. However, when epidemiologic study clearly shows the existence of a school- or classroom-centered outbreak, IG may be given to those who have close personal contact with patients.

4. Institutions for custodial care. Living conditions in some institutions, such as prisons and facilities for the developmentally disabled, favor transmission of hepatitis A. When outbreaks occur, giving IG to residents and staff who have close contact with patients with hepatitis A may reduce the spread of disease. Depending on the epidemiologic circumstances, administration of prophylaxis can be limited to parts of the facility or can involve the entire institution.
5. Hospitals. Routine IG prophylaxis for hospital personnel is not indicated. Rather, sound hygenic practices should be emphasized. Staff education should point out the risk of exposure to hepatitis A and emphasize precautions regarding direct contact with potentially infective materials.[13]

   Outbreaks of hepatitis A among hospital staff occur occasionally, usually in association with an unsuspected index patient who is fecally incontinent. Large outbreaks have occurred among staff and family contacts of infected infants in neonatal intensive care units. In outbreaks, prophylaxis of persons exposed to feces of infected patients may be indicated.
6. Offices and factories. Routine IG administration is not indicated under the usual office or factory conditions for persons exposed to a fellow worker with hepatitis A. Experience shows that casual contact in the work setting does not result in virus transmission.
7. Common-source exposure. Immune globulin might be effective in preventing foodborne or waterborne hepatitis A if exposure is recognized in time. However, IG is not recommended for persons exposed to a common source of hepatitis infection after cases have begun to occur in those exposed, since the two-week period during which IG is effective will have been exceeded.

If a foodhandler is diagnosed as having hepatitis A, common-source transmission is possible but uncommon. Immune globulin should be administered to other foodhandlers but is usually not recommended for patrons. However, IG administration to patrons may be considered if (a) the infected person is directly involved in handling, without gloves, foods that will not be cooked before they are eaten; (b) the hygienic practices of the foodhandler are deficient; and (c) patrons can be identified and treated within two weeks of exposure. Situations where repeated exposures may have occurred, such as in institutional cafeterias, may warrant stronger consideration if IG use.

For postexposure IG prophylaxis, a single intramuscular dose of 0.02 mL/kg is recommended.

Hepatitis B

Hepatitis B virus (HBV) infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma worldwide. The frequency of HBV infection and patterns of transmission vary markedly in different parts of the world. In the United States, western Europe, and Australia, it is a disease of low endemicity, with only 0.1% to 0.5% of the population being virus carriers and infection occurring primarily during adulthood. In contrast, HBV infection is highly endemic in China and Southeast Asia, sub-Saharan Africa, most Pacific islands, and the Amazon Basin; in these areas, 5% to 15% of the population carry the virus, and most persons acquire infection at birth or during childhood. In other parts of the world, HBV is moderately endemic, and 1% to 4% of persons are HBV carriers. Recommendations for prophylaxis of hepatitis B will vary in accordance with local patterns of HBV transmission. The recommendations that follow are intended for use in the United States.

Hepatitis B infection is caused by the HBV, a 42-nm, double-shelled deoxyribonucleic acid (DNA) virus. Several well-defined antigen-antibody systems have been associated with HBV infection (Table 1). HBsAg, formerly called Australia antigen or hepatitis-associated antigen, is found on the surface of the virus and on accompanying 22-nm spherical and tubular forms. HBsAg can be identified in serum samples 30 to 60 days after exposure to HBV and persists for variable periods. The various subtypes (adr, adw, ayw, ayr) of HBsAg provide useful epidemiologic markers. Antibody against HBsAg (anti-HBs) develops after a resolved infection and is responsible for long-term immunity. Anti-HBc, the antibody to the core antigen (an internal component of the virus), develops in all HBV infections and persists indefinitely. IgM anti-HBc appears early in infection and persists for six or more months; it is a reliable marker of acute or recent HBV infection. The hepatitis B e antigen (HBeAg) is a third antigen, presence of which correlates with HBV replication and high infectivity. Antibody to HBeAg (anti-HBe) develops in most HBV infections and correlates with lower rates of infectivity.

The onset of acute hepatitis B is generally insidious. Clinical symptoms and signs include various combinations of anorexia, malaise, nausea, vomiting abdominal pain, and jaundice. Skin rashes, arthralgias, and arthritis can also occur. Overall fatality rates for reported cases generally do not exceed 2%. The incubation period of hepatitis B is long—45 to 160 days (average, 60 to 120 days).

HBV Infection in the United States

The estimated lifetime risk of HBV infection in the United States varies from almost 100% for the highest-risk groups to approximately 5% for the population as a whole. An estimated 200,000 persons, primarily young adults, are infected each year. One fourth become ill with jaundice; more than 10,000 patients require hospitalization; and an average of 250 die of fulminant disease each year. Between 6% and 10% of young adults with HBV infection become carriers. The United States currently contains an estimated pool of 500,000 to 1,000,000 infectious carriers. Chronic active hepatitis develops in more

Table 1 – HEPATITIS NOMENCLATURE

Abbreviation	*Term*	*Comments*
		Hepatitis A
HAV	Hepatitis A virus	Etiologic agent of "Infectious" hepatitis; a picornavirus; single serotype.
Anti-HAV	Antibody to HAV	Detectable at onset of symptoms; lifetime persistence.
IgM anti-HAV	IgM class antibody to HAV	Indicates recent infection with hepatitis A; positive up to 4-6 mo. after infection.
		Hepatitis B
HBV	Hepatitis B virus	Etiologic agent of "serum" or "long-incubation" hepatitis; also known as Dane particle.
HBsAg	Hepatitis B surface antigen	Surface antigen(s) of HBV detectable in large quantity in serum; several subtypes identified.
HBeAg	Hepatitis B e antigen	Soluble antigen; correlates with HBV replication, high titer HBV in serum, and infectivity of serum.
HBcAg	Hepatitis B core antigen	No commercial test available.
Anti-HBs	Antibody to HBsAg	Indicates past infection with and immunity to HBV, passive antibody from HBIG, or immune response from HBV vaccine.
anti-HBe	Antibody to HBeAg	Presence in serum of HBsAg carrier suggests lower titer of HBV.
Anti-HBc	Antibody to HBcAg	Indicates past infection with HBV at some undefined time.
IgM anti-HBc	IgM class antibody to HBcAg	Indicates recent infection with HBV; positive for 4-6 mo. after infection.
		δ-Hepatitis
δ virus	δ-virus	Etiologic agent of δ-hepatitis; may only cause infection in presence of HBV.
δ-Ag	δ-antigen	Detectable in early acute δ-infection.
Anti-δ	Antibody to δ-antigen	Indicates past or present infection with δ-virus.
		Non-A, non-B hepatitis
NANB	Non-A, non-B hepatitis	Diagnosis of exclusion. At least two candidate viruses; epidemiology parallels that of hepatitis B.
		Epidemic non-A, non-B hepatitis
Epidemic NANB	Epidemic non-A, non-B hepatitis	Causes large epidemics in Asia, North Africa; fecal-oral or waterborne.
		Immune globulins
IG	Immune globulin (previously ISG, immune serum globulin, or γ-globulin)	Contains antibodies to HAV, low titer antibodies to HBV.
HBIG	Hepatitis B immune globulin	Contains high titer antibodies to HBV.

than 25% of carriers and often progresses to cirrhosis. Furthermore, HBV carriers have a risk of developing primary liver cancer that is 12 to 300 times higher than that of other persons. It is estimated that 4,000 persons die from hepatitis B-related cirrhosis each year in this country and that more than 800 die from hepatitis B-related liver cancer.

The role of the HBV carrier is central in the epidemiology of HBV transmission. A carrier is defined as a person who is HBsAg-positive on at least two occasions at least six months apart. Although the degree of infectivity is best correlated with HBeAg-positivity, any person positive for HBsAg is potentially infectious. The likelihood of developing the carrier state varies inversely with the age at which infection occurs. During the perinatal period, HBV transmitted from HBeAg-positive mothers results in HBV carriage in up to 90% of infected infants, whereas 6% to 10% of acutely infected adults become carriers.

Carriers and persons with acute infection have highest concentrations of HBV in the blood and serous fluids; less is present in other body fluids, such as saliva and semen. Transmission occurs through percutaneous or permucosal routes. Infective blood or body fluids can be introduced by contaminated needles or through sexual contact. Infection can occur in settings of continuous close personal contact, such as in households or among children in institutions for the mentally retarded, presumably through inapparent or unnoticed contact of infectious secretions with skin lesions or mucosal surfaces. Transmission of infection by transfusion of contaminated blood or blood products has been greatly reduced since the advent of routine screening with highly sensitive tests for HBsAg. HBV is not transmitted through the fecal-oral route or by contamination of food or water.

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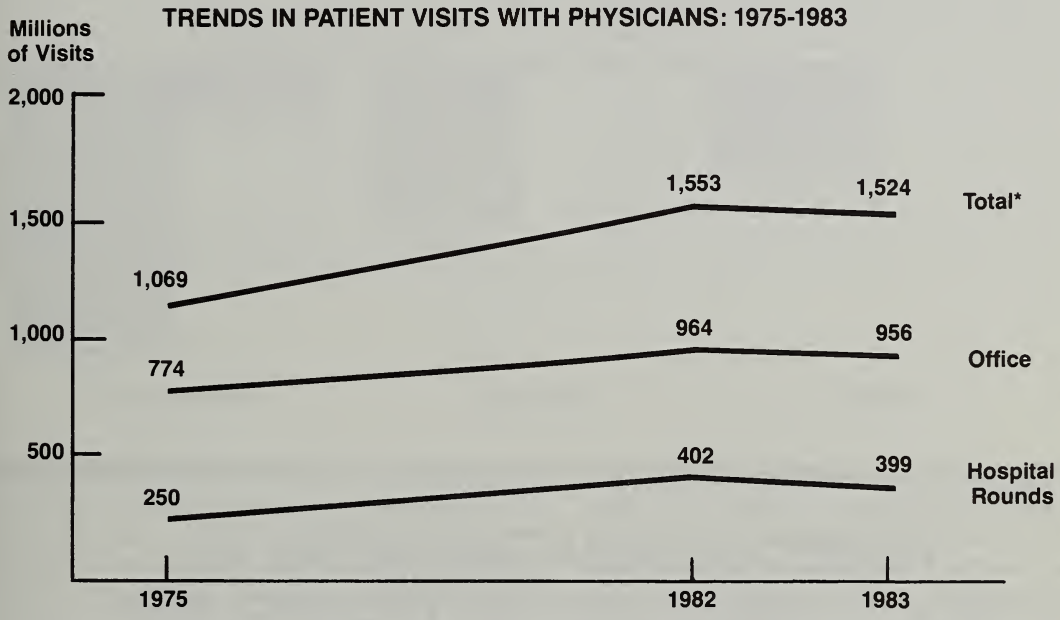
Utilization of Physician Services Declining

Trends in Patient Visits With Physicians: 1975-1983

AMA CENTER FOR HEALTH POLICY RESEARCH

Figure 1


TRENDS IN PATIENT VISITS WITH PHYSICIANS: 1975-1983

*Includes office visits, visits on hospital rounds, hospital outpatient and emergency room visits and visits in all other settings.

Utilization Trends and Variations

This report presents physician-based data on utilization trends and geographic variations. Specifically, it examines trends in patient visits with physicians, as well as variations in office visits per physician, hospital discharges per physician, and the length of stay of patients discharged by the average physician across the four census regions. The key result is that between 1982 and the first half of 1984, the most recent data available, there have been almost continuous declines overall and in all regions of the country, in the utilization of physician services in the office as well as in the hospital inpatient setting. This may signal a slowdown in growth in the health care sector.

Trends

Figure 1 shows that total patient visits with physicians by the U.S. population increased from just over one billion in 1975 to approximately 1.5 billion in 1982. This growth, however, appears to have ended in 1982. Between 1982 and 1983, total visits—which include office visits, visits on hospital rounds, hospital emergency rooms, outpatient departments and other settings—showed a slight decline. Office visits and visits on hospital rounds, the most common types of patient visits, exhibit the same pattern as total visits, showing a period of growth from 1975 to 1982, but declining slightly after 1982. There has also been a shift in the composition of visit sites. While visits other than those in the office or on hospital rounds accounted for only 5% of the total in 1975, they represented 11% in 1983.

The annual percentage increase in total physician visits between 1975 and 1982, as shown in Figure 2, was 5.5%.

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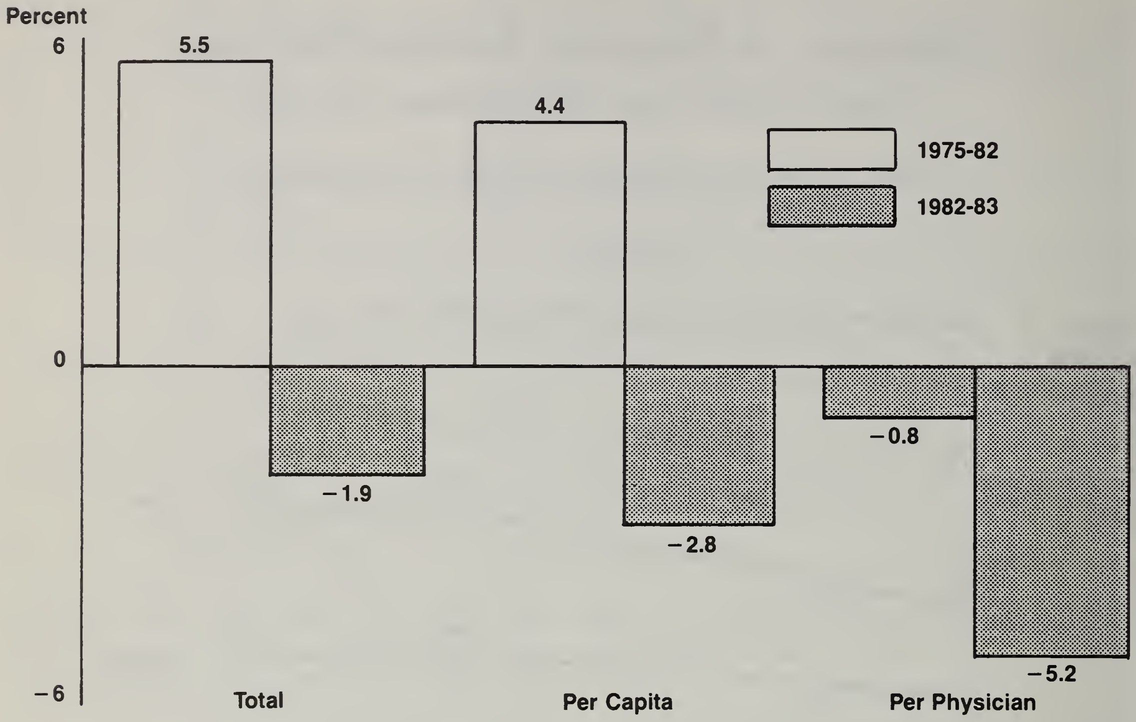
The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

Figure 2

ANNUAL PERCENT CHANGE IN TOTAL PATIENT VISITS WITH PHYSICIANS 1975-1983



However, between 1982 and 1983 total visits declined by nearly 2 percent. In spite of the increase in total visits from 1975 to 1982, the rapid growth in the number of physicians contributed to a slight percentage decline in the annual number of the visits per physician (0.8%). From 1982 to 1983, the downward trend in the number of visits per physician accelerated by 5.2 percent.

Regional Variations

The remainder of this report focuses on regional variations and changes in utilization per physician between the first half of 1983 and the first half of 1984. Since 1983, weekly office visits per physician have continued to decline. For the United States overall, Table 1 shows a 5 percent decline between the first half of 1983 and the first half of 1984. Declines occurred in all four census regions with the smallest declines in the North Central and Southern regions and the largest declines in the Northeast and the West.

The rank ordering of regions by volume of weekly office visits per physician did not change between 1982 and 1983. Visits were highest in the South and the North Central, while the low visit regions were the West and the Northeast. Regions with lower weekly visits showed the greater decline in visits.

Hospital utilization experiences of the typical physician, as reflected in hospital discharges and average length of stay per physician, between the first half of 1983 and the first half of 1984 are presented in Table 2. This table shows that for the United States overall, there were declines in hospital discharges per physician per week and average length of stay of patients discharged of 6.1 percent and 6.2 percent respectively. Declines in discharges and lengths of stay occurred in all four census regions. The South showed the largest decline in discharges per physician at 8.7 percent. This decline was of sufficient magnitude to move the South out of the position of highest discharge region which it held in the first half of 1983.

Table 1

OFFICE VISITS PER PHYSICIAN PER WEEK 1ST HALF 1983 AND 1ST HALF 1984

	1st Half 1983	*1st Half 1984*	*Percent Change*
United States	79.3	75.3	−5.0%*
Northeast	71.0	65.4	−7.8*
North Central	82.4	80.1	−2.7
South	85.0	82.1	−3.4
West	75.1	70.0	−6.7*

*Statistically significant at the .05 level.
SOURCE: First and second quarter SMS surveys, 1983 and 1984.

Physician-based SMS data show that the Northeast is the region with the longest average length of stay for the typical physician and the West is the shortest length of stay region. This regional pattern is similar to that reflected in hospital-based American Hospital Association data and population-based Medicare data. The Northeast, also showed a smaller decline in length of stay than the other regions: 4 percent versus approximately 8 percent for the other regions.

Table 2

HOSPITAL DISCHARGES AND LENGTHS OF STAY OF PATIENTS DISCHARGED BY THE AVERAGE PHYSICIAN—1ST HALF 1983 AND 1ST HALF 1984

	1st Half 1983	*1st Half 1984*	*Percent Change*
	Hospital Discharges Per Physician Per Week		
United States	4.9	4.6	−6.1%*
Northeast	3.8	−7.3	
North Central	5.6	5.3	−5.3
South	5.7	5.2	−8.7**
West	3.9	3.7	−5.1
	Average Length of Stay of Patients Discharged in the Last Week		
United States	6.3	5.9	−6.3%*
Northeast	7.2	6.9	−4.1
North Central	6.5	6.0	−7.6
South	6.3	5.8	−7.9
West	5.3	4.9	−7.5

*Statistically significant at the .05 level.
**Statistically significant at the .1 level.
SOURCE: First and second quarter SMS surveys, 1983 and 1984.

Discussion

Overall, these data indicate that there has been a decline in patient visits per physician and a shift in the composition of visit sites away from the office into other settings. The pattern of regional differences in office visits has not been substantially altered. A decline in hospital inpatient utilization is also shown in these physician-based data. These trends suggest a slowdown in growth and change in the composition of the health care sector. If they continue, then competitive pressures can be expected to increase as the market tightens.

Only data from 1975 were collected through the AMA's Tenth Periodic Survey of Physicians. The half year 1983 and 1984 data are from pooled first and second quarter SMS surveys of representative samples of all non-federal patient care physicians, excluding residents for the respective time periods. The 1983 sample included interviews with 5,188 physicians and achieved a pooled response rate of 62.5 percent. The 1984 sample included 5,210 physicians and achieved a pooled response rate of approximately 61.9 percent.

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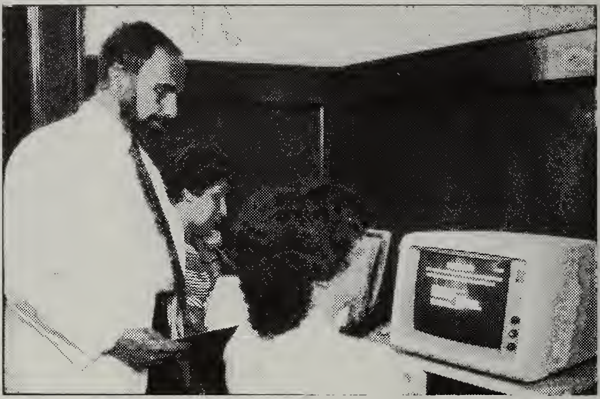

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The President's Page

Elevating Your Horizons

This is the year for increased communication by the Connecticut State Medical Society with its membership and for increased contact of our membership with the public.

The first step to implement this program was taken on September 7, 1985 when the first Leadership Conference sponsored by the Society was held. Attending the Conference were County Presidents, County Officers and Executives, Chairmen of CSMS Committees, Councillors, Chairmen of Specialty Societies, members of the House of Delegates, Chiefs of Hospital Staffs, and selected County Leaders. The Conference was highlighted by the appearance of Harrison L. Rogers, M.D., President of the American Medical Association. Topics for discussion included an update of all of the major issues confronting our membership including the activities of the CSMS, CPRO, physician unions, physician practice patterns, federation membership, pending legislation, countersuits, and professional liability.

The purpose of the CSMS Leadership Conference is to impart to the leaders of our Society an up-to-date global overview of all the forces which are impacting on the doctor-patient relationship. The sound and fury of the Conference will be to no avail if we do not translate the lessons of the proceedings into action.

The next step is the formation of panels of speakers in each County who will deliver our message to the public. The thrust will be to inform and educate the public of the changes in the environment of medicine and how these changes are directly affecting the delivery of care and the relationships of doctors to patients. The County Presidents will act as an Advisory Committee to the President during the course of the year and will be in charge of directing and monitoring the activities of the Speaker's Panels. I urge you to support this program! Given all the potential avenues of improving our public image, "stumping the State" and meeting the public in a live one-on-one basis provides the best opportunity to state our positions and our goals.

I needn't remind you that the environment of medicine is in a dynamic turbulent state of flux. The litany of the events of the upheaval which is occurring is well known to everyone. Complex and impersonal systems are attempting to replace the traditional physician-patient relationship. Allocation of resources are being designated by economic considerations. All sorts of schemes are being devised in order to cut costs while assuming that service will remain available and that the standard of care will remain unchanged.

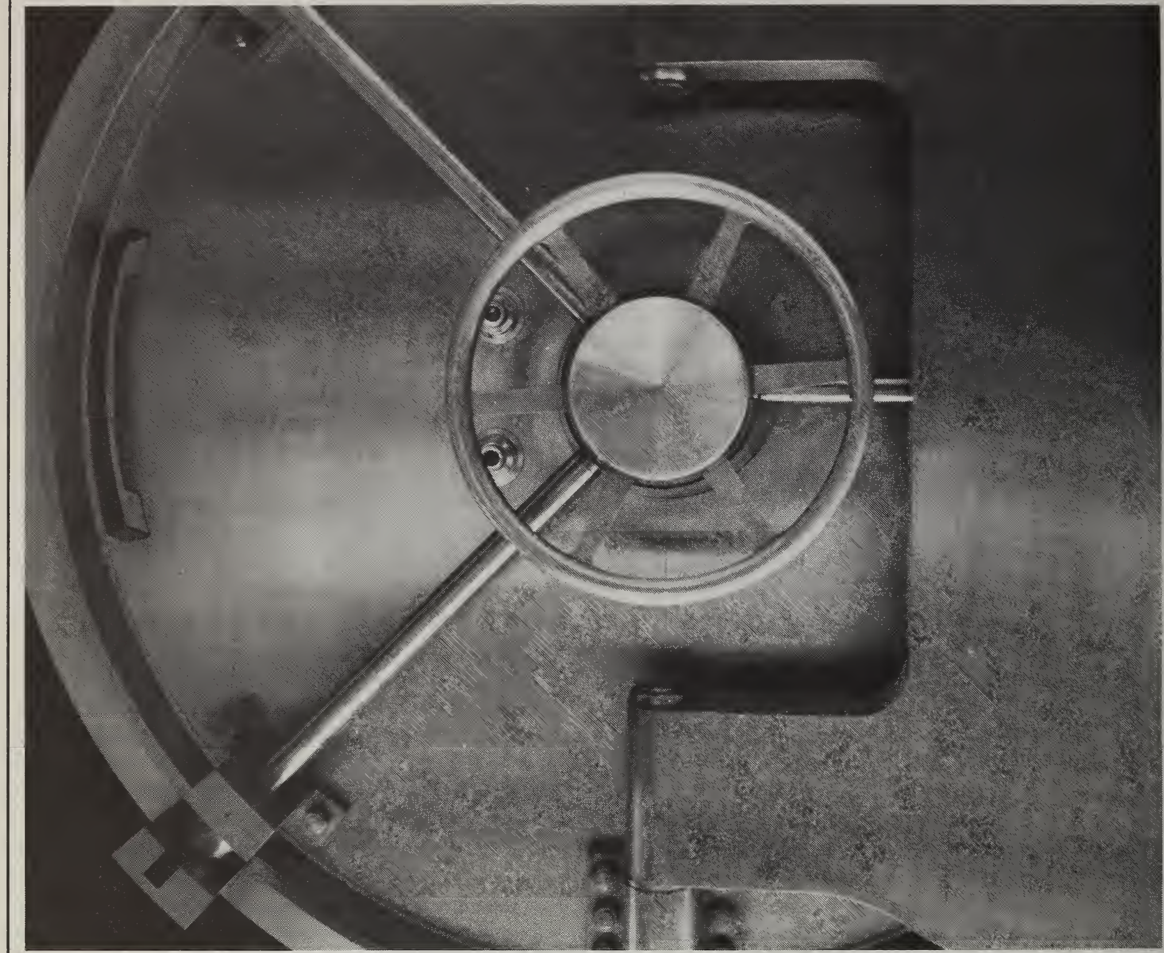
The rapidly changing environment of medical practice is producing anger, denial, insecurity, and depression in the minds of physicians. While attempting to maintain a high standard of care in a cost conscious budgetary environment, physicians are struggling to avoid violating their own ethical principles. In some instances, economic survival is at stake and physicians are beginning to say "Enough is Enough."

Many physicians feel that organized medical societies are unable to reverse present day trends. Consequently, they are seeking new ways to preserve the concept of independent practice. The question is being asked, "What is Wrong with Organized Medicine"? It is very easy to criticize the performance of the Connecticut State Medical Society. Just remember, however, that the CSMS is not a structure on the corner of 160 St. Ronan Street. The CSMS is people; it is you and I—individual physicians. When we criticize the CSMS, we are criticizing ourselves!

The anonymity of each individual physician can be energized into action during this coming year. I believe in strength in numbers, but it is important to provide strength to the numbers. This will be achieved by our Society's keeping the numbers informed and providing the programs and vehicles through which they are able to best demonstrate leadership and strength.

If you believe that the performance and representation of organized medicine and the Connecticut State Medical Society is not satisfactory and if you believe that "Enough is Enough" and your level of frustration tolerance has been exceeded, stop criticizing yourself, contact your County President, and volunteer your expertise and services to help reverse the present day trends. If your County President does not have an assignment for you, contact me!! This is the year to elevate your horizons in terms of responsibility and leadership!

William A. Whalen, M.D.
President



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Reflections on Medicine

Retreat to Virtue

ROBERT U. MASSEY, M.D.

"Physicians' public image continues to decline, according to a report—filed by the AMA House of Delegates."[1]

"My experiences have prompted me to concur with physicians who conclude that it's more difficult than ever to practice 'good' medicine. Some see no alternative but early retirement or a change in profession to escape the pressures."[2]

"It is speeding some physicians into early retirement and causing others to withdraw from high risk procedures," said AMA Executive Vice-President James H. Sammons, M.D., in his address to the House of Delegates at this year's annual meeting. He was referring to the high and rising cost of liability insurance; Purtilo in the quotation above had in mind the "immensity of ethical problems facing physicians."

Add to these worries the anticipated effect of DRGs on the work of hospitals and physicians and on their patients: "DRGs have been introduced to cut health care costs and they probably will do so. But if our concerns are valid, the human cost will be unconscionable."[3]

I suppose I should not have been surprised to find this announcement in my mail:

> "The Board of Directors, at its June 19, 1985 meeting, direct[ed] that a committee be formed immediately to set in motion the formation of a physicians' union in Hartford County."

American medicine turned into a business [corporatization is the word], and now trade unionism! Ironical that with the labor unions in decline everywhere else our profession should now be confessing that it is after all only a trade and needs the protection that a union grants. What are we to say to the medical students now? Perhaps their surprise would be nothing compared to ours; trade or profession, business or calling, the differences may be only in the words. Yet I believe that students' idealism, being newer, is more intense though perhaps not stronger. They must be worried, and they should be.

This year's, or this decade's, crop of problems are more serious than the former "crises in medicine" which have fixed our attention since the doctor shortage was discovered in the 1950s. We have been told that they can be solved only by more regulation or by more competition, or some combination of both, which seems like folly to those of us who see neither applying as neatly to medicine as to the insurance industry. Perhaps we are asking the wrong questions, setting up the wrong problems.

"We doctors know
a hopeless case if—listen: there's a hell
of a good universe next door; let's go."[4]

That will only do for those of us along in years who are about to retire anyway, or for the small number who in desperation have contemplated defection, but for those like our students whose careers will stretch into the 2030s, and for all the others in between, the high calling to which they have dedicated their lives, this "youngest science," will need their protection and nurture. Until better schemes than competition, restructuring, marketing, regulation, and trade unionism are thought of, it may be time to turn inward and cultivate the virtues. I am not suggesting a retreat into some kind of scientific pietism; I know how ethicists get uneasy when someone brings up the subject of virtue, but history and experience suggest that laws and ethical systems without virtue are flimsy contraptions, holding operations at best.

Virtues have to do with what we are as well as what we do; they are private affairs, determining how we behave when no one else is around; I believe you have to start with them when you set about to remake the system. There are grand unifying virtues like integrity and charity; simpler ones like prudence and courtesy. We can all think of those important for our professional work: benevolence, respect, and fairness. Capacity for hard work, reliability, compassion, and good judgment would be others. With more humility and cheerfulness the image problem might go away. Goethe thought that the "shudder of awe is humanity's highest faculty." Maybe he learned that when he was studying medicine at Strasbourg; no matter, for physicians and scientists the shudder of awe can never be far away, and cultivating it may be the best place to start.

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4. cummings ee: one times one.

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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LAW, MEDICINE AND PUBLIC POLICY

Implementing Connecticut's Living Will Legislation: The Promise and the Problems

JOSEPH M. HEALEY, J.D.

Concern about potential civil or criminal liability for withholding or withdrawing life support systems has been exacerbated by the general concern which physicians and hospital administrators have about the current malpractice "crisis." A statute such as Connecticut's recent "death with dignity" statute[1] has as one of its major goals to describe the circumstances under which such actions may be taken without fear of liability. Such efforts are useful in encouraging physicians and hospital administrators to honor the requests of patients about the use of medical and technological interventions without allowing an exaggerated fear of liability to contaminate good judgment. There is a danger, however, that this focus on addressing the fears of providers may lead to compromise or to neglect of the people whose interests should be at the center of such legislative initiatives—the patients. In several respects, our new statute is flawed in this regard and the promise offered by such legislation may be overwhelmed by the problems caused by it.

There is a preliminary question concerning the extent to which such statutes are necessary or desirable. As I described in my last two columns, the rights to consent and to refuse treatment are clearly rooted in the common law right of self-determination and the constitutional right of privacy. Such rights do not evaporate when the person becomes incompetent. Rather, since the *Quinlan* case, it has been generally accepted that they may be exercised by a legally appropriate surrogate whose duty it is to implement the wishes of the patient when known and to act in the patient's best interest, if the patient's wishes are not known. A living will is one mechanism by which a currently competent adult may direct a surrogate or the responsible health providers about treatment and care decisions which arise when the adult is unable to make them.

Absent a statute, the conduct of the health provider who follows the written directive of a once competent adult who has now become incompetent would be evaluated in light of the principle of self-determination and the right of privacy. The absence of a statute does not mean that following such directives will result in liability, only that there is not *automatic* immunity for the caregivers involved. The existence of a statute clarifies the circumstances under which caregivers will be given that immunity from liability. It is important to bear in mind that there have been no cases in which following such directives has resulted in civil or criminal liability and it is unlikely that such liability would result, assuming good faith efforts by the health provider to ascertain and to follow the patient's wishes.

The Connecticut statute in its present form has many weaknesses. Among the most prominent is the provision requiring the informed consent of the next of kin. This provision may have been intended to reduce the possibility that disgruntled family members might file suit against health providers who honor patient requests with which some or all of the family members have disagreement. Whatever the intent, the effect is to give the next of kin veto power over the exercise of self-determination by the patient and to undermine the exercise of autonomy by the patient which led to the use of the living will in the first place. A second major flaw is the exclusion of pregnant women from the application of the act. From a constitutional perspective, the state has little justification for denying the pregnant, terminal ill patient the same right to refuse treatment as other patients, at least until the fetus achieves viability. There are serious practical limitations as well, especially the limits to a doctor's actual knowledge of pregnancy at early stages. The end result is that the statute has a series of weaknesses which threaten to overshadow the attempt to ascertain and implement the wishes of the patient. Physicians and administrators should be aware of these difficulties and avoid them in carrying out the spirit as well as the letter of the law.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCE

1. Public Act No. 95-606.

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Editorials

That Inexorable Margin of Error in Medicine

There are innumberable references in the medical literature about percentage figures by which diagnostic tests are expected to be in error. Radiological or serologic tests, Paps, scannings, the EKG, sigmoidoscopy or other endoscopic examinations—all have postulated margins of false results.

Several points can be made in connection with this grievous and persistent reliability barrier. One is that the public is largely unaware of its existence and places an unrealistic faith in the dependability of medical tests. The expected rate of error applies at least as much to physical examinations that do not include elaborate scientific equipment. By varying margins, negative findings do not exclude disease; and positive tests may be false positives. Many diagnostic techniques have this feature of imperfection, even in the hands of the most competent practitioner.

The public's unawareness of the deficiencies of medicine at its best would require an educational campaign, but this cannot very well be done by the individual physician without affecting his own status and perhaps his reputation in the community. Were he to explain to his patients that the tests he is going to do or did do, carry a margin of error of say 7.5%, many of his patients would probably want to go to another physician whose tests *are* reliable.

The word "error," and admission of error have a disturbingly negative effect when applied to medicine's public relations. A positive statement—such as the level of confidence to which one can rely on a test—sounds more reassuring. An exercise test of the heart provides diagnostic assistance to a reasonable, though not dependable, level of confidence. The exercise EKG may give 20% false results, but put a better way, "it is 80% reliable."

The public's assumption that engaging a physician's services means an "implied contract to diagnose properly and early" is in conflict with reality. If an individual physician is caught in the legal web and tries to explain the pervasiveness of the margin of error in medicine, his defense sounds lame and unconvincing. Modern medicine has the trappings of a precise science. Its accomplishments have been dangerously oversold.

The often quoted precise figures of expected percentages of error, these too are subject to margins of error. It is misleading to state that thermography misses 70% of breast lesions, mammography 15%, and clinical examination is in error by 20 percent. Percentages are a function of the stage of a lesion or disorder. In very early cancer of the lung, the breast, and of many internal organs, the error rate is close to 100 per cent. A lesion, though it exists, may not be recognizable by any means. At late stages recognition approaches 100 per cent, at least in the more accessible organs. And there is every stage in between.

Even in the final stages of disease, does the diagnostic reliability approach 100%? Pathologists tell us that at the time of death less than 88% of the ultimate diagnoses are confirmed by autopsies. A Swedish pathologist from a top notch institution alleges that, in a study of 400 consecutive deaths, he found a 25% rate of major diagnostic error from autopsies. To the pathologist, clinical diagnoses are often merely educated guesses.

Perhaps we should start at the state level with public education that includes information on medicine's limitations. This would be a deviation from the usual practice of dwelling mostly on achievements. But if examinations and tests have, roughly speaking, an inevitable margin of error of 7.5% overall, and autopsies in the best institutions here and abroad show error rates of over 10% of final diagnoses, ought not this fact be brought home to the public and the judiciary, along with the conclusion that one cannot contract for something that often cannot be delivered?

Hans H. Neumann, M.D.

Wilton, CT

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

The Beaumont Bicentennial Symposium

November 22, 1985

In celebration of the 200th anniversary of William Beaumont's birth in Lebanon, Connecticut, The Beaumont Medical Club has initiated several activities to make both the general and medical public aware of the process and evolution of scientific knowledge. One of our planned activities is a symposium on the history of science and medicine in which the broader implications of Beaumont's contribution is related to a more general understanding of scientific observation and experimentation.

Beaumont's birthplace has been preserved in Lebanon, Connecticut and as an historic site (maintained by the Lebanon Historical Society) is significant in the annals of medical history. Here, he grew up and his schooling prepared him for the two-year apprenticeship with a physician in St. Albans, Vermont and began his military career in the War of 1812. As an army surgeon, he was assigned to Fort Mackinac Island where he treated a young French-Canadian, Alexis St. Martin, for a gunshot wound of the stomach. The wound healed but left a permanent opening to the stomach. For four periods over eight years, Beaumont made a careful scientific analysis of digestion and gastric secretions on St. Martin. His precise documention of results, were published in an 1833 book titled "Experiments and Observations on the Gastric Juice and the Physiology of Digestion." This study was widely influential in Europe as well as in the United States.

Today, in the United States, scientific exhibits associated with Beaumont and his work are found in many places, including St. Louis, Mackinac Island, and Madison, Wisconsin. Aside from the Beaumont Medical Club at Yale University, both military and civilian hospitals have been named for him in recognition of his contribution to scientific and medical knowledge, and, therefore, improved patient care. The 500-bed military hospital in El Paso, Texas, and the 1000-bed civilian hospital in Detroit, Michigan, are both named for him.

Beaumont provides a scientific physician role model for young people; books and articles about his life have been used in elementary education, particularly in some of the midwestern states. For Connecticut, this 200th year of his birth is an ideal occasion to call attention to this son of Connecticut whose work represents an important contribution to the development of scientific medicine.

The Beaumont Bicentennial Symposium scheduled for Friday, November 22, 1985, at the Historical Medical Library, Yale School of Medicine. Our goal is to attract an audience of the general public, students and occupational/professional groups. The young students will be alerted to the symposium in their public and private schools and colleges through written contact with faculty and use of posters and media segmented on the age and school groups identified. Individuals working in the occupational and professional categories will receive announcements directed through employers' (posters) libraries, hospitals and local professional societies. The promotional approach will be to encourage the attendance of retired citizens through specific poster announcements at senior citizen housing projects, public service radio messages, and other media directed to that age group. Our goal is to obtain an audience of 200 to 250 individuals in attendance, including physicians interested in their heritage.

The Symposium enjoys the support of the Connecticut Humanities Council and of Blue Cross/Blue Shield of Connecticut.

For more information contact Susan Wheeler, Historical Medical Library, Yale School of Medicine, 333 Cedar St., New Haven, CT 06510. The telephone number is (203) 785-4260 or 785-4354.

David F. Musto, M.D.

President
Beaumont Medical Club

Special Notices

Brachytherapy 1985
Basic Considerations, New Development, Perspectives

Tuesday, November 5, 1985

9:00 a.m. registration

Jane Ellen Hope Building, Room #110
Yale School of Medicine
(enter at 333 Cedar Street, New Haven)

AMA Category I accreditation

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For further information, telephone the Office of Graduate and Continuing Education, Yale School of Medicine: (203) 785-4578.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*
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CALL

SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1985 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, North Haven, commencing at 12:30 P.M. on Wednesday, November 20.

William A. Whalen, Jr., M.D.
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

Mark Your Calendar

CONNECTICUT STATE MEDICAL SOCIETY
SEMI-ANNUAL MEETING - HOUSE OF DELEGATES
Wednesday, November 20, 1985
RAMADA INN
NORTH HAVEN, CT

******

CONNECTICUT STATE MEDICAL SOCIETY
194th ANNUAL MEETING
PARK PLAZA HOTEL
NEW HAVEN, CT

******

HOUSE OF DELEGATES
Wednesday, May 7, 1986

****

ANNUAL SCIENTIFIC ASSEMBLY
OF THE SOCIETY
Thursday, May 8, 1986

****

PLAN NOW TO SAVE THE DATE

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Full time Emergency Medicine or Family Physician/Internist with E.R. experience to join busy ambulatory medical center in central Connecticut. Superior salary and benefits. Great hours. Send C.V. to: Med-HELP Medical Center, 539 Farmington Ave., Bristol, CT 06010, or call (203) 584-8900.

FAMILY PRACTICE

Established, prepaid staff model HMO seeks an experienced B/E or B/C family practitioner to staff our Wallingford Health Center. CHCP has 40,000 members and is affiliated with Yale-New Haven Medical Center. New salary schedule and liberal benefit package. Opening available September 1, 1985 or negotiable. Send C.V. and salary requirements to: Medical Director, Community Health Care Plan, Inc., 150 Sargent Dr., New Haven, CT 06511. EOE, M/F.

B/C or B/E Family physician for young progressive group practice in Western Connecticut. Highly desirable area. Send CV to: Brookfield Family Medicine Center, 940 Federal Rd., Brookfield, CT 06804.

Family physician is seeking a full time family physician to work in a medical facility in a beautiful shoreline community. No night call. No hospital call. The practice is rapidly expanding. Experience in industrial medicine would be helpful. Send C.V. to CSMS, c/o FP/NN.

INSTITUTIONAL MEDICINE

Internist wanted as full-time staff physician for a 500-bed multi-licensed, JACH approved geriatric institution and for a continuing care retirement community in Central Connecticut. Geriatric experience preferred. Will work standard workweek, rotation of evening and weekend call. Send resume with salary requirements to: CSMS, c/o IM/BLS.

INTERNAL MEDICINE

Well-known group model Health Maintenance Organization seeking a well-trained, highly motivated general internist for a full-time position in the Stamford area. Contact R.S. Lyss, M.D., at (914) 682-7720.

INTERNAL MEDICINE/FAMILY PRACTICE

CENTRAL CONNECTICUT area. Excellent opportunity for B/C or B/E internist or family practice physician in Burlington, just 20 minutes from Hartford. Near Boston, New York City. Possibility of solo or partnership arrangement. General income guarantee and benefits. Send CV to Megan Dineen, Bristol Hospital, Brewster Rd., Bristol, CT 06010 or call 9:00 to 5:00 (203) 589-2000, ext. 579.

MISCELLANEOUS

HMO PHYSICIANS. The Community Health Care Plan will open a staff model HMO in Stamford, CT in January 1986. CHCP is a network of staff model HMOs throughout southwestern Connecticut offering competitive salary and fringe benefits to its medical staff. Seeking Board-certified or eligible physicians in all specialties, especially General Internists, Pediatricians, Obstetricians/Gynecologists, General Surgeons, and Radiologists. Send CV to Dr. Stanley Kramer, Medical Director CHCP, 1010 Washington Blvd., Stamford, CT 06901, or call Dr. Kramer at (203) 324-6999.

HOSPICE PHYSICIAN. Position available to be part of the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44 bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut license required. Board Certification preferred. Full-time position but part-time applicants may be considered. Send C.V. to John M. Stober, Director of Human Resources. The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. E.O.E.

OBSTETRICS/GYNECOLOGY

B/C or B/E. Seeking third associate. Yale affiliated 325 bed community hospital. All the advantages of a Connecticut shoreline community. Send C.V. To Robert Spitz, M.D., 342 Montauk Ave., New London, CT 06320.

PART TIME

Neurologists and Orthopedists for Social Security Disability evaluations. Contact Robert P. Coletti, Medical Relations Coordinator, Bureau of Disability Determination, 600 Asylum Ave., Hartford, CT 06105 or call 566-4902.

PEDIATRICS

Excellent private practice opportunity for Board Certified Pediatrician in northwestern Connecticut. Service area population approximately 35,000. Contact Paul E. Graff, President, Winsted Memorial Hospital, 115 Spencer St., Winsted, CT 06098, or call (203) 379-3351 ext. 270.

PRACTICE FOR SALE

INTERNAL MEDICINE AND CARDIOLOGY 42 year old office practice for sale following retirement. Interested parties write: CSMS, c/o SALE/KK and replies will be forwarded.

Pediatric practice for sale due to retirement July 1986. Well established—Central Connecticut—Close to Hartford and New Haven. Terms negotiable. Write the CSMS Placement Service, c/o SALE/DD.

PRIMARY CARE

Southeastern CT area—Full and part-time positions available in Walk-In Medical Center in Groton/New London area. Seeking licensed physicians for day, evening, and weekend positions. Send reply to CSMS Physician Placement, c/o PC/LL.

RADIOLOGY

Part-time radiologist, board eligible or certified for private office practice in greater Hartford area. Please send CV to CSMS, RAD/CC.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

FAMILY PRACTICE

July '86. Age 27. Nat'l bds. MD, University of Rochester, Rochester, NY; Int. and Res., York Hospital, York, PA. Prefers group or industrial type practice in a medium-sized community. Write, James L. Forsberg, M.D., 1433 Fourth Ave., York, PA 17403.

FAMILY PRACTICE—Continued

July '86. Age 28. Nat'l bds. MD, Albert Einstein College of Medicine, NY; Int. and Res., Stony Brook University, NY. Prefers solo or group type practice in a small to medium-sized community. Interested in all aspects of Family Medicine with the exception of Obstetrics. Write, Lanny Moskowitz, M.D., 665 #93 Belle Terre Rd., Port Jefferson, NY 11777.

Jan. '86. Presently in practice. Age 35. Nat'l bds. MD, University of Colorado; Int. and Res., Kaiser Hospital, Fontana, CA. Prefers group, associate or institutional type practice in a medium to large-sized community. Will consider OB. Write, Barry R. Hansen, M.D., 919 Emerson Pl., Claremont, CA 91711.

July '86. Presently in practice. Age 32. Nat'l bds. AB cert. MD, Columbia University, College of Physicians & Surgeons; Int., Institution of Medicine/ Wilford Hall USAF Medical Center; Res., (FP) Creighton University/St. Joseph Hospital. Prefers group, associate or HMO type practice in a medium-sized community. Has had some experience with administration, management as Chief of Family Practice Service. Write, B. William Kopynec, M.D., W. 9609 Nelson Ave., Nine Mile Falls, WA 99026.

GENERAL PRACTICE

Sept. '85. Licensed in Connecticut. Age 33. Nat'l bds. AB cert. MD, UConn, Farmington; Int., Griffin Hospital, Derby; Res., Connecticut Valley Hospital, Middletown. Also interested in psychosomatic medicine and rehabilitation medicine. Prefers group, associate, institutional or industrial type practice. Write, Gary D. Gorman, M.D., P.O. Box 1604, Middletown, CT 06457.

Aug. '85. Age 43. FLEX. MD, University of Louvain, Belgium; Int., University of Louvain Hospitals; Res., West Suburban Hospital, Oak Park, IL. Has no preference to type of practice. Write, Thomas D. Coyne, M.D., 101 Moss Hill Rd., Jamica Plain, MA 02130.

GENERAL SURGERY

Jan. '86. Age 33. Presently in practice. AB elig. MD, King Edward Medical College, Lahore, Pakistan; Int., Lincoln Hospital Medical Center, Bronx, NY; Res., Lincoln-Misericordia affiliation, Bronx, NY. Prefers solo or group type practice in a medium to large-sized community. Write, M. Farrakh Ali Khan, M.D., 785 Oak Ridge Dr., Lisbon, ND 58054.

Immediately available. Presently in practice. Age 42. MD, University of Mosul, Iraq; Int., University of Rochester, NY; Res., Waterbury Hospital, Waterbury, CT. Prefers solo, group or associate type practice. Write, CSMS, c/o JK/SUR.

Aug.'85. Licensed in Connecticut. Presently in practice. Age 65. AB elig. McGill University, Canada; Int. and Res., St. Vincent's, Bridgeport, CT. Prefers solo or industrial type practice in a small to medium-sized community. Write, CSMS, c/o PH/SUR.

July '85. Age 39. FLEX. AB elig. MD, Universidad Autonoma de Guadalajara, Guadalajara, Jalisco, Mexico; Int. and Res., Flushing Hospital and Medical Center, Flushing, NY. Prefers solo, group, associate, institutional or academic type practice in a large-sized community. Write, Anthony J. Menichino, M.D., 82 Niagra Falls Blvd., Buffalo, NY 14214.

INTERNAL MEDICINE

July '86. Age 30. FLEX. AB elig. MD, University of Rome, Rome, Italy; Int. and Res., Framingham Union Hospital, Framingham, MA. Prefers group or associate type practice. Write, Thomas A. Hanna, M.D., 16 Trinity Drive, Milford, MA 01757.

Aug. '86. Age 36. Nat'l bds. AB elig. MD, George Washington University, Washington, DC. Int. and Res., University of Alabama Hospitals. Prefers solo, group, or associate type practice. Write, Les Gavora, M.D., 1206 Sharpsburg Circle, Birmingham, AL 35213.

July '86. Licensed in Connecticut. Age 28. Nat'l bds. AB elig. MD, University of Pennsylvania School of Medicine; Int. and Res., Hartford Hospital, Hartford, CT. Prefers group or associate type practice. Write, Eric L. Rosenberg, M.D., 100 Laura Lane, Apt. C-2, Rocky Hill, CT 06067.

Oct. '85. Age 29. FLEX. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital, Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional, or HMO type practice. Write, Nancy Irene Hoffmann-Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

Oct. '85. Age 36. Nat'l bds. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional or HMO type practice. Write, Dom P. Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

CARDIOLOGY. July '86. Nat'l bds. AB cert. MD, Hahneman University, Philadelphia, PA; Int., Res. and Fellowship, Long Beach Va Medical Center, Long Beach, CA. Experienced in angioplasty, pacemakers, nuclear medicine and doppler/echocardiography. Prefers group or associate type practice. Write, Brian C. Swirsky, M.D., 311 Ocean Ave., Apt. A, Seal Beach, CA 90740.

GASTROENTEROLOGY. July '86. Age 30. FLEX. AB cert. MD, Georgetown University School of Medicine, Washington, DC; Int. and Res., St. Elizabeth's Hospital, Tufts University, Brighton, MA; Fellowship, The Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC. Prefers group, associate or institutional type practice. Write, Thomas P. McMahon, M.D., Brookway West Condominium #E-8, Lewisville, NC.

PULMONARY. July '86. Age 30. Nat'l bds. AB cert. (IM), AB elig. (PUL). MD, University of Connecticut Health Center, Farmington, CT; Int. and Res., McGaw Medical Center, Northwestern Memorial Hospital, Chicago, IL; Fellowship, Cedars-Sinai Medical Center, Los Angeles, CA. Preference is for a pulmonary practice either hospital-based, a subspecialty group or a multi-specialty group. Write, Harlan R. Weinberg, M.D., 337 N. Palm Dr., #8, Beverly Hills, CA 90210.

PULMONARY. July '86. Licensed in Connecticut. Age 30. Nat'l bds. AB cert. MD, Johns Hopkins, Baltimore, MD; Int. and Res., University of Chicago, Chicago, IL; Fellowship, Yale-New Haven Hospital. Prefers group or associate type practice. Write, Ilene L. Rosenberg, M.D., 574 Skiff St., North Haven, CT 06473.

PULMONARY. Immediately available. Presently in practice. Age 32. AB Cert. MD, University of Bombay, Bombay, India; Int. and Res., Jewish Hospital and Medical Center, Brooklyn, NY; Fellowship, Coney Island Hospital, Queens, NY. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Viswanath P. Vasudevan, M.D., 102-12 65th Ave., Apt. #D-64, Forest Hills, NY 11375.

PULMONARY. July '86. Age 30. Nat'l bds. AB cert. MD, Duke University; Int. and Res., Vanderbilt; Fellowship, NYU and Vanderbilt. Prefers group or associate type practice in a medium to large-sized community. Write, Jon Jay Tumen, M.D., 171-A Kenner Ave., Nashville, TN 37205.

RHEUMATOLOGY. July '86. Age 29. Nat'l bds. AB cert. MD, Mount Sinai School of Medicine; Int. and Res., Mount Sinai Hospital, NYC; Fellowship, Mount Sinai Medical Center. Prefers group or associate type practice. Write, Richard P. Crane, M.D., 1249 Park Ave., #17B, New York, NY 10029.

OBSTETRICS/GYNECOLOGY

Jan. '86. Licensed in Connecticut. Presently in practice. Age 54. AB cert. MD, Indiana University; Int., Indianapolis General Hospital; Res., California Lutheran Hospital. Prefers group, associate or institutional type practice in a small to medium-sized community. Write, Leonard J. Burman, M.D., 4212 Via Alondra, Palos Verdes Estates, CA 90274.

RADIOLOGY

Immediately available. Licensed in Connecticut. Age 47. AB cert. MD, National University, Bogota, Columbia; Int., St. Mary's Hospital, Waterbury, CT; Res., Bridgeport Hospital, Bridgeport, CT; Desires associate or institutional type practice. Write Efrain Coronado, M.D., 6257 Gardenview Court, Autumn Green, Orlando, FL 32822.

The Connecticut Tumor Registry: Yesterday, Today and Tomorrow

JOHN T. FLANNERY, B.S. AND DWIGHT T. JANERICH, D.D.S., M.P.H.

ABSTRACT—The Connecticut Tumor Registry (CTR) has completed 50 years of cancer registration in Connecticut which makes it the oldest population based tumor registry in the United States. Initial efforts to collect cancer data began in 1930 in New Haven and eventually, with the help of the Connecticut State Medical Society and other interested groups, resulted in a statewide cancer reporting system in the Connecticut Department of Health Services. The CTR is a member of the NCI-SEER Program which is a network of population based cancer registries located in various areas of the United States which monitor cancer in over 20 million people.

Recent goals adopted by the National Cancer Institute pertaining to reduction in the mortality rate due to cancer through improvements in the control of cancer offers the CTR an important opportunity to participate in the plans to reach these goals and form the base for a new era of cancer progress in the state and in the nation.

The Connecticut Tumor Registry (CTR) will be celebrating 50 years of continuous cancer reporting and follow-up in residents of Connecticut in 1985 which makes it the oldest population-based cancer registry in the United States and one of the oldest in the world. Since 1935, the registry has been part of the Connecticut Department of Health Services and has information on over 400,000 tumors stored on computer and available for research use and is currently annually following 86,000 cancer patients.

Recognized as one of the most valuable research resources in the world, the CTR has participated in numerous state, national and international studies of cancer. Over 240 articles and publications have been published based on data from the CTR. Since 1973, the CTR has been a member of the SEER program of the National Cancer Institute which is a network of 11 population based cancer registries located in various areas of the United States which monitor cancer incidence and survival in over 20 million people.

The earliest efforts to routinely collect cancer data in Connecticut were initiated in 1930 by a group of physicians, health professionals and layman in New Haven who, with the cooperation of the New Haven Board of Health, organized the Cancer Committee of New Haven. Although the committee's original objective was to develop a cancer education program for New Haven, they also responded to alarming statistical trends that showed that New Haven had one of the highest cancer mortality rates in New England. In the final report of 1935, the committee noted that the mortality rate for New Haven residents had increased from 66 to 180 per 100,000 population between 1900 and 1934.[1]

As the committee proceeded to analyze data from the three hospitals in New Haven, they found that New Haven was becoming a center for cancer treatment with a corresponding high proportion of the more difficult cases. Over 48% of the patients treated were not residents of the city. With this in mind, the committee expanded and reformulated their objectives. Cancer clinics in both Grace and New Haven hospitals were organized. Uniform records were designed for the two clinics and staff instructed in the maintenance of records for cancer patients. Since the hospitals were unable to assume the financial burden of cancer patient follow-up and a uniform approach to data collection was essential, the committee assumed the responsibility for follow-up. Thus the initial educational objectives evolved to include assistance to practicing physicians and hospitals in obtaining information on their cancer patients and providing the data to the

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JOHN T. FLANNERY, B.S., Chief; Connecticut Tumor Registry Department of Health Services, Hartford, CT. DWIGHT T. JANERICH, D.D.S., M.P.H., Medical Director, Connecticut Tumor Registry Department of Health Services; Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine.

American College of Surgeons for verification of five year cures.

The work of the Cancer Committee of New Haven was recognized throughout the state and in May, 1933 the State Medical Society adopted a resolution summarizing their concerns and considerations and appointed the first Tumor Study Committee. The significant sections of the resolution are as follows:

> Whereas, the greatest hope of reducing the increasing mortality from this group of diseases lies in diagnosis and treatment in the early state; and:
>
> Whereas, the public through education is becoming more and more insistent upon availability of facilities where these fundamentals in the management of cancer cases can be fulfilled, and:
>
> Whereas, the medical profession and the hospitals are the only forces capable of furnishing the needed service in this field, and must assume the full responsibility for the immediate initiation and conduct of this: therefore be it:
>
> Resolved that the Connecticut State Medical Society shall appoint a Tumor Committee whose function it shall be to survey the existing conditions and stimulate interest in the movement for cancer control in accordance with these programs or in accordance with such modifications thereof as will be best met by the needs of the state.

The appointment of the Tumor Study Committee was the first step in the development of a statewide cancer control program. With the cooperation and support of all the hospitals in the state, the committee worked to coordinate cancer activities in the state and in 1935 was instrumental in the passage of Senate Bill 101 which was signed into law in June 1935. The law read as follows:

> The State Department of Health is authorized to make investigations concerning cancer, the prevention and treatment thereof, and the mortality therefrom, and to take such action as it may deem will assist in bringing about a reduction in the mortality due thereto.

With the new legislation, the Connecticut Health Department created the Division of Cancer and other Chronic Diseases in December, 1935 as a unit within the Preventable Disease Section. The new Division acted in close cooperation with the State Medical Society's Tumor Study Committee and focused on three objectives; a) to conduct morbidity and mortality studies of the disease, b) to maintain facilities for the care and treatment of cancer patients, and c) to insure diagnosis and treatment at the earliest possible moment. It is interesting to note that the Tumor Study Committee changed its name in 1949 to the Cancer Coordinating Committee and remains an active force today in cancer research and control in Connecticut under the current chairmanship of Dr. Arthur Knowlton.

In 1941 the tumor registry began operating statewide. A team from the Division of Cancer and other Chronic

EXCERPTED FROM VOLUME I, NO. 1 OF THE JOURNAL OF THE CSMS; AUGUST, 1936:

REPORT OF THE COMMITTEE ON TUMOR STUDY

May 20, 1936: CSMS Annual Meeting

Thomas H. Russell, M.D., New Haven; Chairman

Mr. President and Gentlemen of The House of Delegates:

Your committee is able to report considerable progress during the past year [1935-1936]. It has held five meetings. Much of its work is being carried on through two sub-committees: A Scientific Committee and a Publicity Committee.

Association of Conn. Tumor Clinics

One important forward step was made in the formation of the Association of Connecticut Tumor Clinics. This association was organized September 18, 1935. Under the by-laws of the organization the chairman and the secretary of the [C.S.M.S.] State Tumor Committee are the chairman and secretary respectively of the Association of Connecticut Tumor Clinics. The purposes of this association are the exchange of ideas, the standardization of records, the clarification of pathological nomenclature, and the improvement and possible standardization of treatment.

The annual meeting of the Association of Tumor Clinics is to be held in conjunction with the [C.S.M.S.] Clinical Congress. Its work is being performed by three active committees: Record Committee, Pathology Committee, and Therapy Committee. The chairman of the Record Committee is Dr. Philip G. McLellan; the Therapy Committee, Dr. A.W. Oughterson and the Pathology Committee, Dr. Joseph O. Collins.

The Committee on Records, under the chairmanship of Dr. McLellan, has worked out, in cooperation with the State Board of Health, standard record forms to be used by the various tumor clinics in operation in Connecticut. This will be of great value to the Clinics themselves in maintaining good records and will assist

Diseases visited each Connecticut hospital and abstracted information on each cancer patient admitted during the six-year period from 1935-1940. Care was taken to be sure that no case was registered that had been diagnosed with cancer prior to January 1, 1935. The original copy of each of these abstracts was kept in the hospital in order to establish a cancer registry in the hospital. While the abstracting was in progress, the team also trained the tumor clinic secretary for the work to be performed in the future.

After the cancer records for the period 1935-1940 were obtained, the records for patients diagnosed 1941 and later were abstracted by the tumor clinic secretary and sent to the central state registry. As hospitals were added to the list of those reporting to the state, abstracting of cancer cases was carried back to admissions in 1935 if the hospital was in existence at that time.[2] This reporting system continued essentially unchanged to the present time.

From the beginning, a concerted effort was made to follow each person reported to the tumor registry through the participating hospitals at least once each year during the remaining life of the individual. Follow-up was and continues to be conducted for two basic purposes:

1. To stimulate continued medical supervision of the cancer patient in order that recurrences of the disease and new primary tumors may be found and treated at the earliest possible stage and
2. To provide data for the analyses of survival in relation to treatment and other relevant factors.

Although recent follow-up efforts by the Connecticut Tumor Registry have included sophisticated computer linkage to files such as the National Death Index, Motor Vehicle License Files and the Health Care Finance Administration, the private physician is still the most important source of valid and complete follow-up information on the cancer patient.

From 1941, when Connecticut hospitals first provided cancer data until 1971 the comprehensive data base was maintained through voluntary physician and hospital response to the requests of the Health Department as authorized by the 1935 law. The legal requirement for registration became effective in March, 1971 when the Regulations of the Department of Health Services were amended to read as follows:

> Section 19-36-2:
>
> Each general, special and chronic disease hospital licensed under chapter 333 of the general statutes shall report, on forms furnished by the State Department of Health, such information as the Department requires concerning diagnosis, stage of disease, medical history, laboratory data, tissue diagnosis, radiation, surgical or other methods of treatment, and annual lifetime follow-up on each cancer patient at such times are necessary to maintain the Connecticut Tumor Registry.

(Continued from inset on previous page)

the State Board of Health in the survey it is making of the cancer situation in Connecticut. Most of these clinics have already adopted this standard record form.

Conn. Tumor Registry

The sum of $10,000 was voted by the Legislature last year [1935], with the endorsement of your committee, to enable the State Board of Health to carry out a cancer program in Connecticut, this money to be used from July 1, 1935 to June 30, 1937. In addition the sum of $6,683.00 has been allotted by the Federal Government under Title VI, Public Health Service Section of the Social Security Act, to be used in Cancer activities. These funds allow the State Department of Health to employ a full time physician, a full time assistant tabulator and the necessary funds for travel, incidentals, etc. A very valuable statistical survey of cancer conditions throughout the State is now being carried out, and information hitherto unavailable will soon be on file.

Education for Prevention

While the treatment of Cancer is a problem for the practicing physicians and existing hospitals of the State, there are certain fields in which the Health Department can function to the greatest benefit in helping to solve this problem. One of these is lay education. With the close cooperation of your committee, the State Department of Health is now carrying out an educational campaign by means of radio, newspapers, pamphlets, lectures and monthly bulletins, in conjunction with our Publicity Committee. The best possible spirit of cooperation exists between your committee and the State Department of Health, in working out a comprehensive program.

While some progress has been made recently along chemical lines in cancer research, our conceptions concerning prevention and treatment still remain unaltered. The public must be educated to a knowledge of the common symptoms of cancer, and to a realization that cancer in an early stage is not hopeless, that periodic health examinations are essential to detect a cancer in an early stage, or better yet in a precancerous stage, that temporizing is fatal and that operation or radium or x-ray are the only methods which offer hope of cure.

The Tumor Clinics in Connecticut have increased from seven in 1934 to ten in 1935 and are now seventeen in number.

Section 19-36-2:

> Failure to comply with the requirements within six months after the end of the calendar year may be cause for suspension or revocation of the license of such hospital.[3]

In September, 1983 the regulation was amended to include mandatory reporting by private pathology laboratories in Connecticut.

The first integration of Connecticut cancer data with information from other parts of the country and the first significant federal financial support began in 1956 when the CTR became part of the National Cancer Institute's End Results Group. The End Results Group was comprised of 11 cancer registries representing various geographical areas of the United States and was organized primarily for the comparison and analysis of cancer survival data. Most of the members of the End Results Group were large hospital registries with the CTR the only population based tumor registry in the group.

In 1973, the National Cancer Institute expanded the scope of the End Results Group and designated nine population based cancer registries including Connecticut as the Surveillance, Epidemiology and End Results Group perhaps better known as the SEER Group. The SEER program required the addition of new data items to the Connecticut cancer data base such as place of birth, an expanded racial/ethnic code, expansion of treatment codes and diagnostic codes, implementation of a new extent of disease code and recently a new site specific surgery code.

Since the CTR was now requiring more information from the hospitals it was necessary to implement more efficient quality control procedures in the areas of abstracting and case finding at the Connecticut hospitals. Field staff from the registry supplemented by quality control staff from the NCI began routine quality control visits to hospitals to assess the quality of reporting to the NCI. Results of recent case finding audits indicate that the reporting from the Connecticut hospitals was better than 99% complete which is a tribute to the competency and dedication of the hospital registry personnel in Connecticut.

Throughout the years, the CTR has experienced a remarkable stability of leadership. Originally the registry was assigned to the Preventable Diseases Unit. Dr. Eugene Lamoreaux served as Director of that division from 1935-1948 and was succeeded by Dr. James Hart who retired in November, 1975.

The first registry director was Dr. Matthew H. Griswold who was appointed in 1935. He was succeeded by Dr. Henry Eisenberg in 1958 who served until his death in 1968. Dr. Barbara Christine assumed the role of Director from November, 1968 until her retirement in February, 1975.

In 1975, the CTR became part of the newly created Division of Health Statistics and Mr. John T. Flannery was appointed to the position of Chief of the Tumor Registry during that same year. The CTR remained part of this Division until 1984 when it again became part of the Division of Preventable Diseases which is under the direction of Dr. Peter Galbraith.

In 1971, discussions were begun among several groups concerned with cancer to explore ways of enhancing the potential of the CTR for research. The principal parties were the State Medical Society, the CTR, the National Cancer Institute, the Connecticut Division of the American Cancer Society and the University of Connecticut and Yale Medical Schools. A planning committee was formed which recommended that a Connecticut Cancer Epidemiology Unit be established in New Haven in close professional association with the Department of Epidemiology and Public Health of the Yale School of Medicine. Funding was to be provided through a contract between Yale and the NCI and Yale would assume responsibility for administrative management and fiscal services.[4]

The Connecticut Cancer Epidemiology Unit (CCEU) began formal operation in January, 1974 with the appointment of Dr. J. Wister Meigs as Director. The long term objective of the CCEU was to make epidemiological studies of cancer incidence and survival with the results used for planning better cancer control methodology. Dr. Meigs was succeeded by Dr. Mary Curnen in July, 1982 and Dr. Dwight Janerich took over as the Director of the CCEU and Medical Director of the CTR in January, 1985.

With the completion of fifty years of active cancer registration behind us, it is an appropriate time to look to the future of the Connecticut Tumor Registry. Data and statistics are only as valuable as their applications and of the uses to which they are put. The coming decades will be a time when we begin to use what we have learned about applied cancer epidemiology from the Connecticut Tumor Registry.

The National Cancer Institute has recently announced new efforts to bring about major improvements in the control of cancer by the year 2000. The efforts will include major new steps in the area of primary and secondary prevention of cancer, as well as continued efforts to improve the effectiveness of cancer treatment. Specifically, the National Cancer Institute has proposed a goal of a 50% reduction in the age adjusted mortality from cancer by the year 2000. The State of Connecticut, with its extensive background information on population based cancer data, offers an important opportunity to participate in the plans to reach these goals.

Plans are now underway for a cooperative research program between the Connecticut Department of Health Services, the University of Connecticut and Yale University, for the development of statewide cancer control research projects. These projects will be designed to deal with the major tumor sites and will seek the cooperation of the National Cancer Institute for implementation of the program. The Connecticut Tumor Registry, through applied cancer epidemiology and modern cancer control practices, will form the basis for a new era of cancer progress in the state and in the nation.

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The International Association of Cancer Registries

The Benefits of a Worldwide Network of Tumor Registries

CALUM S. MUIR, M.B., CH.B., PH.D., FRCPATH, FFCM

ABSTRACT—The International Association of Cancer Registries, founded in Tokyo in 1966, has as the main objectives the development and application of cancer registration and morbidity techniques to studies of defined population groups. A non-governmental organization in official relations with WHO, the Association has members in 51 countries. Major activities include annual scientific meetings and quinquennial publication of the Cancer Incidence in Five Continents monographs in collaboration with the International Agency for Research on Cancer.

The registry can contribute to many facets of cancer control which include service to the cancer patient and his treating physician, evaluation of survival, treatment and screening, estimation of the needs for cancer services, cancer incidence and etiology, measuring the results of intervention, etc. Valuable though such contributions are for the region covered by the registry, when data from registries in other countries and continents are also taken into consideration, this opens a new dimension notably in the realm of formation of etiological hypotheses.

This communication is in two parts: the first describes the origins, objectives, membership and accomplishments of the International Association of Cancer Registries; the second the benefits that derive from cancer registration both nationally and worldwide.

International Association of Cancer Registries

The International Association of Cancer Registries was created in Tokyo in 1966 on the occasion of the IXth International Cancer Congress of the International Union Against Cancer (UICC). Among those present were the late Professor M. Segi, Mr. W. Haenszel and Dr. Sidney Cutler. A constitution and by-laws were drafted and approved at a meeting held in Houston, Texas on 23 May 1970.

Objectives

The objectives of the Association are the development and application of cancer registration and morbidity techniques to studies of defined population groups. The Association hence welcomes to membership organizations and individuals concerned with the collection and analysis of data on cancer incidence and/or the end results of cancer treatment in defined population groups.

The Association is endeavouring to increase awareness, at an international level, of the importance of producing accurate and comparable morbidity and mortality data which can be used with confidence for the generation of etiological hypotheses for cancer and as a basis for epidemiological studies. In addition to these fundamental aspects of cancer control, the Association aims to improve the service provided to the cancer patient and his treating physician by promoting, sound registration practice, follow-up and related activities.

CALUM S. MUIR, M.B., CH.B., PH.D., FRCPATH, FFCM, Deputy Secretary, International Association of Cancer Registries, Chief, Unit of Descriptive Epidemiology, International Agency for Research on Cancer, 150, Cours Albert Thomas, Lyon, France.

Membership: Office Bearers

The membership consists of voting members and associate members. Registries (or organizations) applying for membership are asked to complete a proforma describing their registry (with emphasis on completeness of coverage). The President, General Secretary and Regional representatives (see below) decide whether applicants should be accorded associate or voting membership, the latter designating two individuals to cast votes. The Executive Board consults the voting members not only on the choice of office bearers (see below) but also on questions that may affect the policies of the Association. The membership now comprises (98) voting and (84) associate members.

The membership is distributed as follows: Africa (8), America (55), Asia (21), Europe (84), Oceania (14).

The office bearers comprise the President, the General Secretary and Regional Representatives for Africa, the Asia and Pacific area, South America, Europe and the Near East, and North America. In April 1973 the International Association of Cancer Registries requested the International Agency for Research on Cancer (IARC) to provide a Secretariat for the Association. Following the signature of an agreement to this effect, the Agency has acted as a central Secretariat and an Agency staff member acts as Deputy Secretary. The current office bearers are:

President: Professor K. Shanmugaratnam, Singapore Cancer Registry

General Secretary: Dr. J. Young, SEER Registries, USA

Deputy Secretary: Dr. C.S. Muir, IARC

Regional Representatives:

Africa: Professor R. Owor, Kyadondo County Cancer Registry, Uganda

Asia & Pacific: Dr. J. Ford, New South Wales Cancer Registry, Australia; Professor T. Shigematsu, Fukuoka Cancer Registry, Japan

Europe and Near East: Dr. O.M. Jensen, Danish Cancer Registry, Denmark; Dr. P. Schaffer, Bas-Rhin Cancer Registry, France

North America: Dr. G.B. Hill, Alberta Cancer Registry, Canada; Dr. T. Mack, Los Angeles County Cancer Surveillance System, USA

South America: Professor C. Cuello, Cali Cancer Registry, Columbia

From time to time the Association confers Honorary Membership on those considered to have contributed substantially to Cancer Registration. Such persons include: Sir Richard Doll, Dr. W. Haenszel, Dr. E. Pedersen, the late Professor M. Segi, and Dr. R. Steinitz.

Recognition by WHO

The Association is recognized as a non-governmental organization (NGO) in official relations with WHO and as such has the privilege of sending representatives to selected United Nations meetings as well as to the World Health Assembly and the WHO regional committees. At these meetings the Association representative has the opportunity to make statements on matters pertinent to the interests of the Association and may, on invitation, comment on other agenda items.

The 34th World Health Assembly, held in Geneva in May 1985, called on the global family of non-governmental organizations to support the strategies needed to achieve the goal of Health for All by the Year 2000, and called, in this context, upon the governments of member states to "promote, foster and support the partnership approach by involving non-governmental organizations in policy formulation, planning, implementation and evaluation of national strategies."

Activities

The major activities of the Association are as follows:

Cancer Incidence in Five Continents: The quinquennial production of this monograph in collaboration with IARC is possibly the most important activity of the Association. These publications contain good quality incidence data from registries presented in a standard format. The fourth volume of the series[1] which is regarded as a standard work of reference, provided data collected by 79 cancer registries on 104 populations in 32 countries.

The President of the Association nominates an Association member to the editorial board and a past President of the Association, Dr. J.A.H. Waterhouse, Birmingham and West Midlands Cancer Registry (UK) has been an editor for all four volumes of the Cancer Incidence in Five Continents series published to date. Associated with this publication there have been two surveys of histological patterns for selected cancer sites, information again contributed by Association members.

Scientific Meetings: A most important activity of the Association is the scientific meeting. These have now become an annual event:

1966 Tokyo, Japan
1970 Houston, Texas, USA
1972 Dusseldorf, Federal Republic of Germany
1974 Montecatini, Italy
1978 Buenos Aires, Argentina
1980 Oslo, Norway
1982 Seattle, Washington, USA
1983 Heidelberg, Federal Republic of Germany
1984 Fukuoka, Japan

The 1985 meeting will be held in Hartford, Connecticut, USA to mark the 50th Anniversary of the founding of the Connecticut Tumor Registry. The increasing frequency of meetings indicates the growing interest in cancer registries and their work. Over the years, a meeting format has evolved, namely a structured programme on the first day, followed by a series of proferred papers on the main theme and other topics. The 1984 meeting was held in conjunction with the SEER Registries Programme Review, as will that in 1985. The 1986 meeting of the Association will be held in Budapast, Hungary, in conjunction with the XIVth International Cancer Congress of UICC. This arrangement permits cancer registry staff to broaden their knowledge of malignant disease and clinicians and others to learn more about the work of registries.

Other projects: Members of the Association have collaborated with IARC in providing information about adenocarcinoma of the vagina in young women, on the distribution of malignant tumors of the nose, middle ear and nasal sinuses[2] and on the topical distribution of the malignant melanoma.

In 1978 the Association and IARC published the first formal Monograph on "Cancer Registration and its Techniques,"[3] a Monograph which has been very widely distributed and of which stocks are now exhausted. A second edition is in preparation.

Association members are again collaborating with IARC on the production of a compendium of the computer programmes used in cancer registries. This work, coordinated by Mr. H. Menck of the Los Angeles County Cancer Surveillance System, will be in loose-leaf form, permitting easy up-date. Among the items of information collected are the computer configurations in use, the staff, the workload, the operating system, the compiler, etc. used, the sources of information, the type and content of patient records, data entry, coding, editing and consistency checks, etc.

Benefits of Cancer Registration for Science and Society

A cancer registry can be defined as an organization for the collection, storage, analysis and interpretation of data on persons with cancer.[4] The hospital-based cancer registry undertakes these tasks within the confines of a hospital, or increasingly common, a group of hospitals. The population-based registry is concerned with all newly diagnosed cases of cancer occurring in a population of well-defined composition and size.

The cancer registry is an essential part of any rational programme of cancer control, benefitting not only the individual, but also the society in which he lives. The measures for cancer control include: (a) continuing assessments of the levels of cancer in a population, and of the requirements for the personnel, hospital and other facilities and equipment needed in the diagnosis, treatment and rehabilitation of the cancer patient, (b) evaluation of the effect of early diagnosis and of treatment, (c) identification of the agents causing cancer through epidemiological and laboratory studies and (d) the evaluation of the effect of removing both initiators and promoters from the environment. The cancer registry has a role to play in each of these activities.

Service to the Medical Profession and the Cancer Patient

Cancer registries depend on the willingness of members of the profession to report directly, or indirectly, newly diagnosed cases of cancer. As collaboration is a two-way process, the reporting physician must receive a service in return. The information most appreciated is that of use in his daily work of patient care. This may include reminders that a patient should be seen again on some anniversary date, in other words, initiation of follow-up. The initiation of follow-up is rarely done by the cancer registry itself. Annual listings of patients seen by a physician or service are frequently appreciated, as is help in the preparation of case series for publication. Cancer registries can often provide information about previous treatment for those who are vague about or do not know their medical history.

Survival and Evaluation of Treatment

The hospital-based cancer registry will normally have detailed information on treatment given and on the survival of individual patients. However, such selected case series cannot give a true picture of how all patients with a particular cancer fare. Some hospitals with a reputation for excellence may have rather poor survival, in that they may frequently take over patients who have failed treatment elsewhere. Only the population-based cancer registry, by linking its records to death certificates, is in a position to give a true idea of overall survival.

When comparing the effects of different treatments the only valid method is the controlled clinical control. The hospital registry can be of the greatest assistance in keeping the proper records.

The Provision of Cancer Services

Knowledge of the size of the cancer problem in a given year permits the health planner to estimate the numbers of hospital beds, the type, the level and training of personnel required (a fall in gastric cancer and a rise in lung cancer clearly requires surgeons with different training) and the type of equipment needed. If appropriate records are kept it may be possible to identify where undue delay is occurring between first patient contact and the start of treatment. Rural and urban shifts in population, or changes in the location of population now observed in many large cities with a move to the suburbs, may suggest the optimal location of new hospitals and treatment facilities. Registry records can provide a factual basis for such decisions.

Evaluation of Screening

A great deal of time and money has been spent in the provision of screening for cervical cancer and, more recently, cancer of the breast and large bowel. The reason underlying such endeavours is intuitively appealing, namely the earlier the tumor is detected, the greater the chance of cure. But few screening programmes have been put to the only valid test of efficacy, namely, is mortality from the cancer in question lower among the screened than in the non-screened? The cancer registry by definition is in an ideal position to assist in this assessment if the cases detected at screening are conscientiously reported to the cancer registry. The Danish, Finnish, Icelandic and North-East (Scotland) Cancer Registries[5] have shown what can be done in this respect.

Epidemiology—Incidence

One of the most important contributions that the cancer registry can make is to provide current data for the incidence of cancer by age, sex, occupation, etc. The computation of rates depends on the availability of appropriate denominators although in their absence, proportional incidence ratios may be computed. Depending on the nature of the area it may be possible to compare incidence in urban and rural areas,[6] such differences then being correlated with other aspects of the environment. If histology is recorded, differences in histological type may be examined. If the cancer registry has been in existence for some time, then it may be possible to examine time trends. By looking at the age-specific incidence rates over time it may be possible to forecast future cancer patterns. Thus in Japan at a time when the overall mortality of stomach cancer was rising in around 1955, it was possible to show a decline in mortality for age 40-44, thus heralding the great diminution in risk for this form of cancer.[7]

Epidemiology—Causes

The cancer registry has been increasingly used to uncover the causes of cancer, mainly using the cohort technique in which a large number of persons without cancer are asked questions and these individuals are followed over time to see which of them develop malignant disease. Thus, after time had elapsed, one would find more cases of lung cancer among those smoking than among those who do not. The great advantage of the cohort approach is that replies are not distorted by the presence of disease or by differential recollection as may happen for the case-control study. For certain types of information such as diet, memory tends to be rather poor and more accurate assessments can be obtained by asking about current consumption.

Once the data have been collected, the epidemiologist has only to wait until the diseases of interest appear in those participating in the study. Such investigations are very cheap *if* the means exist to make a link between the cohort members and the cancer registry and/or death certificates. In practice this means having a record of names or unique identification numbers. If cohort members are enrolled now and followed into the future, it will require many years before an answer is obtained, hence, particularly for industrial studies, it is usual to assemble the cohort at some time in the past and follow them till the present day.[8] Although this reduces the time needed to obtain an answer, it is frequently not possible to obtain information, such as the smoking habits of cohort members, which may be needed to interpret the findings. It cannot be too strongly emphasized that if this was the only use made of cancer registries, they would have justified their existence.

Registries may be of assistance in case-control studies by providing a yardstick against which cases interviewed may be compared to assess their representativity. While registries can provide lists of diagnosed cases for research workers to interview once the treating physician's authorization has been obtained, the delays in the registration process for a population are frequently such that such lists are of little use if it is desired to interview in the hospital setting.

Intervention

The most compelling proof of intervention comes when removal of the suspected cause is followed by fall in the incidence of the cancer in question. For some rapidly fatal cancers it may be sufficient to examine death rates but for most, incidence figures are to be preferred. Although when conjugated oestrogens were no longer given to menopausal women in California, the incidence of endometrial cancer fell within six months or so, thus suggesting that these substances were acting as promoters,[9] it usually requires several years before the effects of intervention become apparent and measurable. The effect of treatment can be gauged by comparing incidence and mortality: thus for Hodgkin's Disease while incidence has remained constant in many countries, mortality has fallen substantially, reflecting advances in therapy.

Atlases

In recent years several cancer mortality atlases have been published. These are of great interest but given the varying lethality of cancers of different organs incidence is the preferable measure, as figures are not influenced by possible differences in the effect of treatment, stage at diagnosis, etc. Cancer incidence atlases are thus now being prepared at IARC for Scotland and the German Democratic Republic. The cancer mortality atlases published to date have uncovered striking differences within, for example, the United States[10] and China.[11] The existence of these differentials in risk should lead to further etiological hypotheses to be tested by other means.

Worldwide Aspects

Valuable though a national or regional cancer registry may be, its data become much more useful if they can be compared and contrasted with those emanating from other parts of the world. Differences in incidence are likely to reflect variation in environmental exposures and this concept has given rise to numerous correlation studies in which cancer level is compared with the distribution of risk factors. Thus large bowel cancer correlates well with the proportion of calories derived from animal fat.[12] The observation that the incidence of malignant melanoma is rising in a fair skinned population becomes much more significant if the same holds true for fair skinned populations all over the world. Examination in changes of risk of this cancer by birth cohort shows that successive cohorts born from 1880 onwards show an increase in risk on reaching a specified age.[13] This again suggests that a major risk factor has been in the environment for a long time. That no such rise has been observed in the more pigmented races may again point to etiology.

An interesting observation that can be made by registries is the monitoring of risk from cancer in migrant populations. The changes observed on migration constitute the most compelling evidence that the high risk of gastric cancer in, say, Japanese is not of genetic origin in that this risk falls on migration to the United States. Conversely, the rapid rise in large bowel cancer in these migrants to close to the risk of the US born population points to the existence of agents in the United States environment relatively rare in Japan. These observations were initially based on mortality. The opportunity now exists in several countries to examine, through cancer registries, the possible causes of changes in risk in several migrant populations in a variety of countries. Such populations are in effect in transition from one life style and set of exposures to another. Among the groups suitable for study would be Hispanics to the United States, South Europeans to Australia, and Indians and Pakistanis to Great Britain.[14] Unfortunately these great human experiments are not being exploited as they should be to uncover etiology.

The existence of high levels of cancer of the nasopharynx in Cantonese and intermediate levels in North African populations as well as in Inuit in Alaska, Canada and Greenland, provides not only opportunities to develop hypotheses but also a means of hypothesis verification for, if the distribution of a cancer is not consistent with the distribution of the purported causal agent, then that hypothesis is either incomplete or wrong.[15] Given the known changes in type of food consumed, the recent increase in breast, large bowel and prostate cancer incidence observed in Japan is in consonance with the dietary etiology postulated for these cancers in occidental countries.

When attempting to study rare tumors it is most useful to be able to pool data from cancer registries, as for the study of cancer of the nose, nasal cavities, middle ear, and sinuses mentioned above.[2] Such data pooling can also be advantageously used to address questions which could not be answered or, of best, with imprecision in one centre. To quote but one example, an IARC coordinated study compared the incidence of second primary cancers in women treated for cancer of the cervix by irradiation and other methods.[16] Large radiation doses experienced by over 80,000 women did not dramatically alter the risk of developing a second cancer—at most about 5% of the 3,324 second cancers could be attributed to this cause. Of importance was the finding that only a slight excess of acute and non-lymphocytic leukaemia was found in radiated women and substantially fewer cases were observed than expected on the basis of current radiation effect estimates. It would not have been possible to obtain the exceptionally large numbers of subjects studied or have such long periods of follow-up without pooling data.[16]

A cancer registry is useful; a network of cancer registries is vastly more informative than the sum of the knowledge that each one can provide.

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Bladder Cancer in Connecticut: The Role of Cigarette Smoking and Other Risk Factors

LORAINE D. MARRETT, PH.D., J. WISTER MEIGS, M.D., AND
JOHN T. FLANNERY, B.S.

ABSTRACT—In 1978-1979 a population-based case-control study of bladder cancer was conducted in Connecticut as part of a large collaborative study to investigate a number of risk factors for bladder cancer, particularly use of artificial sweeteners. This report summarizes the results of the Connecticut portion of the study.

In Connecticut, 412 cases of newly diagnosed bladder cancer ascertained through the Connecticut Tumor Registry network, and 881 controls of similar sex-age distribution, were interviewed. Ever smokers of cigarettes, compared to those who never smoked cigarettes, had significantly elevated odds ratios (OR) of 2.8 ($p < 0.01$) and 1.8 ($p < 0.05$) in males and females respectively. Risk increased according to amount smoked from 2.2 ($p < 0.01$) in male smokers of less than 20 packyears (compared to non-smokers) to 3.7 ($p < 0.01$) in male smokers of 40 or more packyears. Comparable OR for women were 1.5 and 3.7 ($p < 0.01$) respectively. Risks were also elevated in both sexes for consumption of more than 1 cup of coffee per day (OR = 1.5 in males, $p < 0.05$; 1.2 in females) and history of bladder infections (OR = 2.6 males, $p < 0.05$; 1.4 in females), particularly if 3 or more such infections had been diagnosed.

In terms of the proportion of bladder cancers in the population attributable to the various factors investigated, cigarette smoking was by far the most important, with 57% of male cases and 27% of female cases attributable to this exposure. Occupational factors appeared to account for only a very small fraction of cases. It is therefore recommended that more public attention be focussed on cigarette smoking as a preventable exposure which could be expected to have a significant beneficial impact on bladder cancer incidence in Connecticut.

In 1973-1977, the state of Connecticut had the highest incidence of bladder cancer in both sexes and the highest male mortality of the eleven areas of the United States which comprised the Surveillance, Epidemiology, and End Results Program (SEER), although two areas (Atlanta and New Orleans) had higher female mortality.[1] In addition, according to the Atlas of Cancer Mortality,[2] three of Connecticut's eight counties had rates of bladder cancer mortality which significantly exceeded the rate for all US males in 1950-1969; no such excesses were apparent for women.

During 1977-1979 the Connecticut Tumor Registry (CTR) of the Connecticut State Department of Health Services and the Connecticut Cancer Epidemiology Unit (CCEU) of Yale University participated in a large collaborative population-based case-control study to investigate the role of several known or suspected bladder tumor risk factors. The purpose of this report is to present the findings of the Connecticut portion of this study, with particular emphasis on the role of cigarette smoking in the etiology of bladder cancer.

Materials and Methods

In late 1977, when evidence that use of artificial sweeteners might be a risk factor for bladder tumor was

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LORAINE D. MARRETT, PH.D., Epidemiologist and Assistant Professor, Ontario Cancer Foundation Epidemiology Research Unit, Department of Preventive Medicine and Biostatistics, University of Toronto, Toronto, Ontario, Canada M5S 1A8. J. WISTER MEIGS, M.D., Clinical Professor, Department of Epidemiology and Public Health, Yale University School of Medicine. JOHN T. FLANNERY, B.S., Chief, Connecticut Tumor Registry, Connecticut State Department of Health Services, Hartford, CT.

Reprint requests to Dr. Marrett.

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beginning to accumulate, the US Congress mandated conduct of a very large epidemiologic study of the issue called the National Survey of Environment and Health (NSEH). The chosen sites of study were the participants of SEER, all of whom, by definition, had population-based cancer registries. These included the SMSAs of Atlanta, Detroit, Seattle-Puget Sound, San Francisco-Oakland, and New Orleans and the states of Connecticut, Iowa, Utah, and New Mexico. The state of New Jersey, although not part of the SEER program, was also included because of its high bladder cancer mortality.

Study methods have been described elsewhere[3, 4] but will be reiterated to include details of Connecticut procedure. All state residents aged 21-84 years who had a histologically confirmed tumor of the bladder newly diagnosed between January 15, 1978 and January 14, 1979 were eligible for inclusion in the study. Cases were identified through the existing mechanisms for reporting to the CTR, with the assistance of the Director of the CTR and the Tumor Registrars/Medical Records personnel of Connecticut hospitals, as well as practising physicians. Individuals with known previously diagnosed lower urinary tract tumors (i.e., tumors of the renal pelvis, ureter, bladder, or urethra) were excluded. Permission to contact a patient was secured from his/her physician before an introductory letter describing the study was sent to the patient by way of the physician's office. Physicians and their staff were highly cooperative in over 99% of case interviews. The letter to the patient was followed by a telephone call from an interviewer to set up an appointment.

Controls were an age- and sex-stratified random sample of the Connecticut population, selected to have a 2:1 control to case ratio and the sex and age (in five-year age groups) distribution expected for the cases on the basis of bladder cancer incidence data reported to the CTR for 1975-1976. Those under age 65 years were selected by random digit dialing of residential Connecticut telephone numbers. This was carried out from the collaborative study center in Maryland where trained telephone interviewers dialed the randomly selected numbers and, after explaining the study, asked for an age-sex census of the household. A random sample of persons from households providing censuses was then chosen. Controls aged 65 years and over were randomly drawn from the files of the Health Care Financing Administration (HCFA) which maintains essentially complete coverage of the older population of this country. All selected controls were first sent an explanatory letter, then were contacted by telephone by an interviewer, as were cases.

All interviews were conducted in person by trained personnel using a structured questionnaire. Unless another venue was specifically requested by the study subject, the interview took place in the subject's home. The interview schedule included questions on several known or suspected risk factors for bladder cancer, including use of tobacco, artificial sweeteners, coffee, hair dyes, medication for tuberculosis, and history of selected urinary tract disorders and occupational exposures. On the subject of smoking, each person was asked whether s/he had ever smoked non-filter cigarettes for a total of six months or more before one year prior to interview; those who had were then asked about all periods of smoking, usual daily number of cigarettes, years smoked at that level, and whether they usually inhaled. This series of questions was repeated for filter cigarette smoking. For other forms of tobacco (cigars, pipes, plugs, and snuff), subjects were asked whether they had used each form for six months or more, at what usual level (number per day), for how many years, and, if appropriate, whether they inhaled. "Never smokers" of cigarettes are those who replied negatively both to the question about smoking non-filter cigarettes for six months or more and to the same question regarding filter cigarettes; "ever smokers" of cigarettes include everyone who answered either question affirmatively. Non-users of any form of tobacco must likewise have replied negatively to these questions for all forms of use. "Ever smokers" are subdivided according to whether they smoked cigarettes at some time during the five years prior to interview ("current smoker") or not ("ex-smoker"). Two measures of amount smoked are considered. "Usual consumption," a measure of intensity, is taken to be the maximum of the reported usual daily numbers of filter and non-filter cigarettes. "Lifetime consumption" is estimated in terms of packyears, as the usual number of daily packs of non-filter cigarettes times the years smoked at that level plus the same function of daily packs and years smoked for filter cigarettes; this constitutes a measure of intensity and duration combined.

Details of information gathered on medical and other lifestyle variables can be found elsewhere.[3, 5-8] With respect to occupational exposures, subjects were asked to give job title, industry and materials handled for each job held for 6 months or more. Then they were asked to review a list of specific substances and to indicate any additional exposures not already reported. Occupations and industries were coded according to the 1970 US Census Codes.[9] For assessing the importance of occupational exposures, groups of "high risk" occupations and materials exposures were identified a priori, based on knowledge of Connecticut industries and jobs, combined with prior reports of suspect bladder cancer risk factors. The literature pertinent to NSEH selections was summarized by Silverman et al[10] and Schoenberg et al.[11] Job titles and industries were excluded if there were no subjects in the Connecticut series with those exposures.

The relative risk is commonly used to indicate the amount of increase in disease risk associated with a given exposure. Thus, a relative risk of 2 means that an exposed person has twice the risk of an unexposed person of having the disease of interest. In this study, the odds ratio (OR), calculated as the cross-product ratio in a two by two table, is used to estimate the relative risk of bladder cancer associated with various factors of interest.[12] The

X^2 statistic is used to assess whether the odds ratio differs significantly from one.

The population attributable risk (PAR) is used as a measure of the proportion of bladder cancer cases in Connecticut which can be attributed to a given risk factor. For each such factor, the PAR is computed as a function of both the relative risk and the exposure prevalence of the factor in the population, here estimated by the odds ratio and the proportion exposed in the controls respectively. [13] Thus, a factor with a large relative risk but a negligible exposure prevalence may have a smaller PAR than an exposure which results in only a slightly increased risk but is very widespread. It should be noted that PARs are not necessarily additive and are negative if a relative risk is less than one, implying a preventive role for the factor under consideration.

Results

Five hundred and sixteen eligible bladder tumor cases were identified, of whom 72 (14 per cent) were either deceased or too ill to be interviewed. Of the remaining 444 cases, 412 (93 per cent) were interviewed. Six hundred and six controls age 65-84 years were selected for interview, of whom 39 (6 per cent) were too disabled to be interviewed and 18 (3 per cent) had died by the time they were contacted; 493 (90 per cent) of the remainder were successfully contacted and interviewed. Response rates for those under 65 years of age are more difficult to estimate. Eighty seven per cent of the residential phone numbers dialed yielded household censuses. From these an age and sex stratified random sample of 441 persons was selected to be contacted again. Of those so selected, 6 had died or were considered too disabled to participate and 388 (89 per cent) of those remaining were interviewed. Table 1 shows the response rates according to case-control status, age and sex. Proportionately more cases than controls of each sex could not be interviewed due to death or severe illness. Also, more older females than males, both cases and controls, did not participate for the same reasons.

Table 2 provides basic demographic and smoking data. The majority of cases are male, as would be expected on the basis of the incidence sex ratio. Male cases and controls are well-matched on age, but female controls are 2.4 years older than cases on average, although this difference is not statistically significant. A higher percentage of cases

Table 1

SEX AND AGE SPECIFIC RESPONSE RATES FOR BLADDER CANCER CASES AND CONTROLS. CONNECTICUT. 1978-1979

Sex/Age	*Ascertained as in Scope #*	*Dead or Incompetent #*	*(% of in Scope)*	*Eligible for Interview #*	*Completed Interviews #*	*(% of eligible)*
			Cases			
Males:						
<65	147	11	(7.5)	136	125	(91.9)
65+	217	34	(15.7)	183	170	(92.9)
Females:						
<65	75	5	(6.7)	70	65	(92.9)
65+	77	22	(28.6)	55	52	(94.6)
			Controls			
Males:						
<65	336	5	(1.5)	331	292	(88.2)
65+	436	38	(8.7)	398	365	(91.7)
Females:						
<65	105	1	(1.0)	104	96	(92.3)
65+	170	19	(11.2)	151	128	(84.8)

Table 2

REPORTED CIGARETTE SMOKING STATUS BY SEX AMONG CASES AND CONTROLS

Cigarette Smoking Status	Male Cases	Male Controls	Female Cases	Female Controls
Never Smoked* #	35	182	45	117
%**	11.9	27.7	38.5	52.5
mean age	66.7	65.9	68.6	67.4
Ever Smoked #	260	475	72	106
%	88.1	72.3	61.5	47.5
mean age	65.3	64.8	58.8	62.1
mean pack years	43.5	40.4	27.9	21.0
mean cigs/day	26.9	27.1	20.9	17.4
Total #	295	657	117	224†
%	100	100	100	100
mean age	65.5	65.1	62.6	65.0

*Never smoked non-filter or filter cigarettes for 6 months or more before one year prior to interview

**% of total cases or controls of given sex

†1 female control had unknown smoking status

than controls of both sexes had smoked cigarettes (88.1% versus 72.3% in males and 61.5% versus 47.5% in females for cases and controls respectively). In addition, case smokers had smoked more pack years on average than control smokers of both sexes. While female case smokers also smoked more cigarettes daily than controls, there was no difference in males. Male smokers, cases and controls, smoked more than females as measured by either cigarettes per day or pack years.

Table 3 shows the distribution of male study subjects and odds ratios according to the type of tobacco smoked. Slight but non-significant risk elevations are evident for men who had smoked only pipes or only cigars, while those who had smoked both had an apparent risk reduction. Men who had smoked cigarettes, however, had a significantly increased risk of bladder cancer compared to those who had never smoked tobacco of any type. Tables 4 and 5 give the odds ratio estimates for cigarette smoking by indicators of smoking habits and age group for male (Table 4) and female (Table 5) bladder cancer

Table 3
TYPE OF SMOKING AND ODDS RATIO ESTIMATES AMONG MALE CASES AND CONTROLS

Type of Smoking	*Cases*	*Controls*	*Odds Ratio*
Never smoked tobacco	22	114	1.0
Smoked pipes only	4	13	1.70
Smoked cigars only	5	23	1.19
Smoked pipes & cigars only	4	32	0.70
Smoked cigarettes only	131	231	2.94**
Smoked cigarettes plus pipes or cigars	128	244	2.72**

**p<0.01

Table 4
ODDS RATIO ESTIMATES (OR) FOR CIGARETTE SMOKING BY INDICATORS OF SMOKING HABITS AND AGE GROUP, MALE BLADDER CANCER CASES AND CONTROLS, CONNECTICUT 1978-1979

Cigarette Smoking Indicator	*All Ages*			*Aged <65 Years*			*Aged 65+ Years*		
	Cases	*Controls*	*OR*	*Cases*	*Controls*	*OR*	*Cases*	*Controls*	*OR*
Never Smoked	35	182	1.0	16	77	1.0	19	105	1.0
Status									
Ever	260	475	2.85**	109	215	2.44**	151	260	3.21**
Ex-smoker	135	284	2.47**	42	115	1.76	93	169	3.04**
Current Smoker	124	188	3.43**	67	100	3.22**	57	88	3.58**
(unknown)	(1)	(3)		(0)	(0)		(1)	(3)	
Lifetime Consumption									
<20 packyears	51	120	2.21**	21	66	1.53	30	54	3.07**
20-39 packyears	63	143	2.29**	31	72	2.07	32	71	2.49**
40+ packyears	140	199	3.66**	55	75	3.53**	85	124	3.79**
unknown	(6)	(13)		(2)	(2)		(4)	(11)	
Usual Consumption									
<20 cigarettes/day	54	114	2.46**	17	38	2.15	37	76	2.69**
20-39 cigarettes/day	139	239	3.02**	57	113	2.43**	82	126	3.60**
40+ cigarettes/day	67	122	2.86**	35	64	2.63**	32	58	3.05**
(unknown)	(0)	(0)		(0)	(0)		(0)	(0)	

**p < 0.01

Table 5
ODDS RATIO ESTIMATES (OR) FOR CIGARETTE SMOKING BY INDICATORS OF SMOKING HABITS AND AGE GROUP, FEMALE BLADDER CANCER CASES AND CONTROLS, CONNECTICUT 1978-1979

Cigarette Smoking Indicator	*All Ages*			*Aged <65 Years*			*Aged 65+ Years*		
	Cases	*Controls*†	*OR*	*Cases*	*Controls*	*OR*	*Cases*	*Controls*†	*OR*
Never Smoked	45	117	1.0	17	38	1.0	28	79	1.0
Status									
Ever	72	106	1.77*	48	58	1.85	24	48	1.41
Ex-smoker	21	43	1.27	9	17	1.18	12	26	1.30
Current Smoker	50	60	2.17**	38	39	2.18	12	21	1.61
(unknown)	(1)	(3)		(1)	(2)		(0)	(1)	
Lifetime Consumption									
<20 packyears	30	53	1.47	19	31	1.37	11	22	1.41
20-39 packyears	21	36	1.52	14	19	1.65	7	17	1.16
40+ packyears	17	12	3.68**	13	7	4.15*	4	5	2.26
(unknown)	(4)	(5)		(2)	(1)		(2)	(4)	
Usual Consumption									
<20 cigarettes/day	27	49	1.43	15	24	1.40	12	25	1.35*
20-39 cigarettes/day	36	49	1.91*	26	29	2.00	10	20	1.41
40+ cigarettes/day	8	7	2.97	7	4	3.91	1	3	1.20
(unknown)	(1)	(1)		(0)	(1)		(1)	(0)	

*p < 0.05
**p < 0.01
†One woman was excluded from all analyses because her smoking status was unknown.

cases and controls. Among men, there was evidence for increases in the risk of bladder cancer with increased usual or lifetime amount of cigarette smoking, within each age group and for all ages. Current smokers had higher risks than ex-smokers. Most excess risks were highly significant. Among women, trends were similar for all ages combined and for younger women, but numbers were smaller and odds ratio estimates differed significantly from one in only a few instances. Women aged 65 years and over showed only moderate excess bladder cancer risk from cigarette smoking. In both sexes, lifetime consumption appeared to be a consistent indicator or risk, with 40 or more packyears almost always associated with 3 to 4 fold increases in risk.

Tables 6 and 7 present exposure rates, odds ratios, and population attributable risks for selected lifestyle, medical and occupational risk variables for male (Table 6) and female (Table 7) bladder cancer cases and controls. These tables show that among Connecticut residents who developed primary bladder tumors in 1978-1979, only cigarette smoking, coffee drinking and history of previous bladder infection were risk factors for bladder tumors in both sexes. The OR for 3 or more compared to no previous bladder infections (not shown) were high, 5.0 for men and 2.5 for women; both were significantly different from one ($p < 0.01$). Artificial sweetener use was associated with a slight decrease in risk for men and a slight elevation for women. The risks from hair dyes and

Table 6

EXPOSURE RATES, ODDS RATIOS (OR) AND POPULATION ATTRIBUTABLE RISKS (PAR) FOR SELECTED VARIABLES, MALE BLADDER CANCER CASES AND CONTROLS, CONNECTICUT, 1978-1979

Risk Variable	*Exposure Level*	*Referent Level*	*Exposure Rate (%) Cases*	*Controls*	*OR*	*PAR (%)*
Cigarette smoking	ever	never	88.1	72.3	2.8[a]	57.2
Artificial sweeteners*	≥10 uses	<10	30.5	37.2	0.7	−10.7
Coffee	>1 cup/day	≤1	81.7	74.7	1.5[b]	27.7
Hair dyes	ever	never	3.8	4.0	0.9	−0.2
TB medication	ever	never	1.0	1.5	0.7	−0.5
Bladder infection+‡	ever	never	16.5	7.1	2.6[b]	10.2
Bladder stones‡	ever	never	3.7	1.1	3.6[b]	2.7
Kidney infection+‡	ever	never	4.8	6.0	0.8	−1.3
Kidney stones‡	ever	never	7.6	7.6	1.0	0.0
"High risk" occupation#	ever	never	5.1	5.6	0.9	−0.6
"High risk" materials§	ever	never	32.2	31.4	1.0	0.0

*Includes artificially sweetened foods and beverages and table top sweeteners

+Diagnosed by a physician

‡At least one year prior to interview

#Includes anyone who ever worked (for ≥6 months) in a "high risk" job, as defined in Table 8

§Ever exposed on the job to dyes, dye intermediates, rubber, leather, printing inks or paints

[a] $p<0.01$

[b] $p<0.05$

Table 7

EXPOSURE RATES, ODDS RATIOS (OR) AND POPULATION ATTRIBUTABLE RISKS (PAR) FOR SELECTED VARIABLES, FEMALE BLADDER CANCER CASES AND CONTROLS, CONNECTICUT, 1978-1979

Risk Variable	*Exposure Level*	*Referent Level*	Exposure Rate (%) *Cases*	*Controls*	*OR*	*PAR (%)*
Cigarette smoking	ever	never	61.5	47.5	1.8[a]	26.7
Artificial sweeteners*	≥10 uses	<10	47.4	44.2	1.1	5.8
Coffee	>1 cup/day	≤1	77.8	74.8	1.2	11.9
Hair dyes	ever	never	49.6	50.4	1.0	0.0
TB medication	ever	never	1.7	0.9	1.9	0.8
Bladder infection+‡	ever	never	36.0	28.6	1.4	10.4
Bladder stones‡	ever	never	0.9	1.8	0.4	−1.1
Kidney infection+‡	ever	never	11.3	7.8	1.5	3.8
Kidney stones‡	ever	never	8.5	2.7	3.4[a]	6.0
"High risk" occupation#	ever	never	6.0	3.6	1.7	2.5
"High risk" materials§	ever	never	14.5	9.8	1.6	5.2

*Includes artificially sweetened foods and beverages and table top sweeteners

+Diagnosed by a physician

‡At least one year prior to interview

#Includes anyone who ever worked (for ≥6 months) in a "high risk" job, as defined in Table 8

§Ever exposed on the job to dyes, dye intermediates, rubber, leather, printing inks or paints

[a] $p<0.05$

tuberculosis medication were absent or very small.

Table 8 presents the occupation and industry titles and code numbers, as defined by the US Census in 1970,[9] that were used to classify "high risk" occupations a priori. Table 6 shows that a priori "high risk" occupations had an OR of 0.9 for men. The a priori "high risk" materials also failed to indicate significant risk. Women experienced slightly elevated risks for both "high risk" occupations and materials, as shown in Table 7. There were too few women exposed to present more detail, but for men, exposure risk by selected materials is given in Table 9. This shows that paint exposures had a small odds ratio (1.4) with an attributable risk of 5.9%. The traditional high risk materials (dye-chemicals, printing inks, rubber, and leather) were not indicated as causes of bladder tumor among men.

Table 9

EXPOSURE RATES, ODDS RATIOS (OR), AND POPULATION ATTRIBUTABLE RISKS (PAR) FOR SELECTED ON-THE-JOB EXPOSURES, MALE BLADDER CANCER CASES AND CONTROLS, CONNECTICUT 1978-1979

	Exposure Rates (%)			
*Exposure**	*Cases*	*Controls*	*OR*	*PAR (%)*
"High risk" materials +	32.2	31.4	1.0	0.0
Dyes/intermediates	7.5	6.5	1.2	1.0
Rubber	3.4	3.0	1.1	0.4
Leather	3.4	3.0	1.1	0.4
Printing Inks	1.4	3.3	0.4	−2.1
Paints	21.7	16.7	1.4	5.9

*Ever exposed on the job, as reported by subjects.

+ Dyes/dye intermediates, rubber, leather, printing inks, and paints.

Table 8

"HIGH RISK" OCCUPATIONS

Occupation			*Industry*	
Title	*Code No.**		*Title*	*Code No.**
Selected engineers	010,011, 013,023		Manufacture of: textile products	307,308, 317,318
Chemist	045			
Chemical or engineering technician	151,162		industrial chemicals	347
			paints	359
Painter	510,511		petroleum & products	377,378
Shoe repairman	542	IN	rubber products	379
Craftsman or craft apprentice	575,571		leather & products	388,389, 397
Dyer	620			
Mixing operative	641		Shoe repair	789
Shoemaking machine operative	664		Garment services	779
Miscellaneous machine operative	690,692			
Foreman	441			
Cutting operative	612	IN	Above industries excluding: Manufacture of textile products	307,308, 317,318
Sewer or stitcher	663		Garment services	779
Unspecified operative	695			
Unspecified laborer	785			

*1970 US Census Codes (9)

Results from the Detroit and New Jersey portions of NSEH indicated bladder cancer risks among vehicle drivers, gas station attendants, and food workers.[10, 11] Therefore, these occupations were studied in the Connecticut portion of this study. Drivers had an OR of 1.4 ($p < 0.05$) with a PAR of 7.9%. Odds ratios for the other two occupations were 0.9 and 1.0 respectively.

Discussion

This case-control study of bladder tumor in Connecticut in 1978-1979 is consistent in outcome with all areas of the NSEH with respect to cigarette smoking as a risk factor for both men and women.[3] From the preventive viewpoint, Tables 4 and 5 indicate not only the high odds ratios for heavy cigarette smoking and the potential benefits of stopping, but also (Table 2) the importance of publicizing the findings among the younger population, especially women, who have not acquired the smoking habit. Thus Table 2 shows that nearly three quarters of male controls had ever smoked, while less than half of the women had a similar history. It is reasonable to guess that the 1978 population attributable risk for women from cigarette smoking (Table 7, 26.7%) would reach that for men (Table 6, 57.2%) if smoking rates, intensities and durations for women were to rise to equal those for men.

The possible role of coffee drinking in causing bladder tumor is also shown, in Tables 6 and 7. Details of these coffee risks were presented by Marrett et al[5] and illustrate some of the uncertainties about coffee as a risk factor. These uncertainties are reflected in the variability of results reported by other investigators.[5, 14] Nevertheless, history of coffee consumption has been associated with bladder tumor occurrence frequently enough to suggest caution in the use of coffee as well as further study of the relationship.

The NSEH questionnaire was designed to allow study of most exposures and conditions that had previously been linked with bladder tumor. It was noteworthy that within the group of prior disorders of the urinary tract there were several positive associations, but only a history of prior bladder infections was associated with an increased risk of bladder cancer for both men and women. Since the odds ratios for such histories were as high as 5.0 for recurrent (i.e., 3 or more) infections, their occurrence would justify careful search for associated tumor of the bladder, or lower urinary tract.[8]

The lack of evidence that artificial sweetener or hair dye use have caused bladder tumor[3, 6] are of interest in light of extensive publicity prior to NSEH.

The Connecticut findings with respect to risks of occupation and/or exposures to suspected high risk materials are especially interesting. Table 6 shows that no excess bladder cancer among men could be attributed to these risk factors in 1978. The findings for the New Jersey portion of NSEH were not as favorable, but in New Jersey, risks from a priori selected high risk occupations and materials were less than had been anticipated.[11] It seems reasonably probable that preventive measures in the workplace have reduced substantially the risks of bladder tumor from industrial exposures among men in Connecticut over the past 40-50 years, during which the State Departments of Health and Labor conducted active industrial hygiene and occupational health programs.

Future freedom from these risks must not be taken for granted. Table 7 shows that women had odds ratios of 1.7 and 1.6 respectively for "ever exposed" to high risk occupations or materials. Table 9 shows that men "ever exposed" to paints had an OR of 1.4 with a PAR of 5.9%. Known bladder carcinogens can be expected to cause bladder cancers in persons who have had significant exposures. If substitution of non-carcinogenic materials is not practicable, exposures to known carcinogens must be kept at minimal levels throughout manufacture and during any subsequent uses in which human exposures may occur.

The risks of cancer from occupational or other environmental exposures will not disappear even if all identified carcinogens are eliminated, because previously unknown hazardous agents and circumstances will be recognized. For example, male drivers of many kinds of vehicles had an OR of 1.4 for bladder tumor and a PAR of 7.9%. Causal factors are unknown, but results from Detroit[10] and New Jersey[11] also indicated excess risks among drivers. The diverse findings of different studies suggest that much more must be learned about bladder tumor development before the circumstances, and combinations of exposures, that promote it can be understood well enough to reduce or eliminate the remaining risks.

The comprehensive nature of this study permits the conclusion that one risk factor for bladder cancer, cigarette smoking, accounted for the major portion of bladder cancer in Connecticut. The many negative or insignificant risks associated with other factors would justify more effort to concentrate public attention on the smoking issue, where significant health benefits could be expected from preventive programs.

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Cancer Incidence in Connecticut: The Last Twenty-Five Years

PAMELA BYRNES, M.S., HOLGER HANSEN, M.D. AND ANTHONY SARDINAS, M.P.H.

ABSTRACT—Data from the Connecticut Cancer Atlas, commemorating the 50th anniversary of the Tumor Registry, describe trends and patterns of cancer incidence in the state and its regions. Total male cancer rates were consistently high in the three most urbanized regions (the Hartford, New Haven, and Bridgeport areas) and consistently low in the eastern, north central and western parts of the state. Female rates showed considerably less regional differences; areas of low rates paralleled the male cancer pattern in the 1960's but lost that advantage thereafter. Overall, male cancer incidence rose by 25 percent during the period. Female rates dropped slightly in the early 1960s and rose thereafter; the increase slowed during the late 1970s.

The Connecticut Cancer Atlas marks the 50th anniversary of the Connecticut Tumor Registry (CTR). Publication will coincide with the meeting of the International Association of Tumor Registries in Hartford this coming December. The Cancer Atlas—a project of the Public Health Research Center which is sponsored jointly by the Connecticut State Department of Health Services and the University of Connecticut Health Center—documents cancer incidence in the state from 1958-1982.

Utilizing CTR and census data, the Cancer Atlas provides two series of age-specific and age-adjusted five-year incidence rates for nineteen specific cancer sites as well as all cancers combined. Series One, beginning with 1958-1962, presents incidence rates for males and females in ten-year age groups. Series Two, starting with 1968-1972, provides rates in five-year age groups for white males, white females, nonwhite males, and nonwhite females. Along with state-wide rates, the Atlas examines cancer incidence for fourteen sub-areas of the state and the five major towns of Hartford, Bridgeport, New Haven, Stamford, and Waterbury. The rates are presented in table form as well as in a series of maps which depict cancer incidence at the area level. This report presents data from the Cancer Atlas for all cancers combined for the fourteen sub-areas and the state as a whole based on the Series One analysis.

Methods

Age-specific cancer incidence rates were constructed from CTR data tapes and U.S. census data. Census data tapes were used for the 1970 and 1980 data, and 1960 census data was entered onto tape manually.[1] Denominators for intercensual years were estimated by linear interpolation. Age-adjusting was done using the U.S. 1970 Standard Million population. Cancer frequencies were averaged over five-year intervals (1958-62, 1963-67, 1968-72, 1973-77, 1978-82). This grouping reduces chance variation, places the census years at midpoint, coincides with the last two five-year analyses of the SEER program, and facilitates cohort analysis of incidence rates which will be available in ten and five year age groups.

Cancer sites were selected according to their epidemiological significance including considerations of the magnitude and nature of occurrence. In general, cancer sites with a sex-specific age-adjusted incidence rate above 5.0 per 100,000 population in 1973-1977 were chosen for analysis along with several additional sites of particular importance in Connecticut. The included

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PAMELA BYRNES, M.S., Instructor in Community Medicine; HOLGER HANSEN, M.D., Professor of Community Medicine; ANTHONY SARDINAS, M.P.H., Assistant Clinical Professor of Community Medicine; all of the Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

Reprint requests to: Department of Community Medicine and Health Care, Division of Epidemiology, University of Connecticut Health Center, Farmington, CT 06032-9984.

From the Public Health Research Center at the University of Connecticut Health Center.

cancers are buccal cavity and pharynx, stomach, colon excluding rectum, rectum and recto-sigmoid, pancreas, larynx, lung and bronchus, skin, breast, cervix uteri, corpus uteri, ovary, prostate, urinary bladder, kidney and renal pelvis, brain, non-Hodgkin's lymphoma, testis, and leukemia.

Fourteen analytic sub-areas of the state, each with an approximate population of 200,000 in 1980, were constructed to facilitate regional cross-sectional and time trend comparisons. Aggregation of towns was based on several considerations: to maintain comparability with existing subdivisions such as health planning areas; to construct geographic units of similar population size to reduce chance variation; and to generate areas with relatively homogeneous socioeconomic characteristics. Towns were grouped according to socio-economic index scores for the years 1960,[2] 1970,[3] and 1980,[4] constructed by the University of Connecticut Department of Agricultural Economics and Rural Sociology. Analysis of the average socioeconomic index scores for the fourteen sub-areas indicated considerable stability in the areas' relative standing.

The maps depict three classes of areas based on rank order (three lower, eight intermediate, three upper rates). In addition, confidence intervals of two standard errors above and below each area rate are contrasted with the respective state average. Time trends are examined by percentage change and regression methods.

Cancer Patterns

Presented here are age-adjusted incidence rates of all cancers combined in each of the sub-areas during the last 25 years. Figures 1 and 2 show the level of cancer incidence in the most recent five-year period (the actual rates are found in Table 1). The three highest male rates, all significantly different from the state average, were found in the three most urbanized regions, the Hartford, New Haven, and Bridgeport areas. Significantly low male rates occurred in the four largely rural areas stretching across the northern part of the state. For female rates the pattern is less pronounced. Only two rates differ significantly from the state average: the high incidence in the New Haven area and the low incidence in the eastern area. The two other high ranking areas are among the socioeconomically leading regions of the state. The spread of cancer rates for males is considerably larger than that for females.

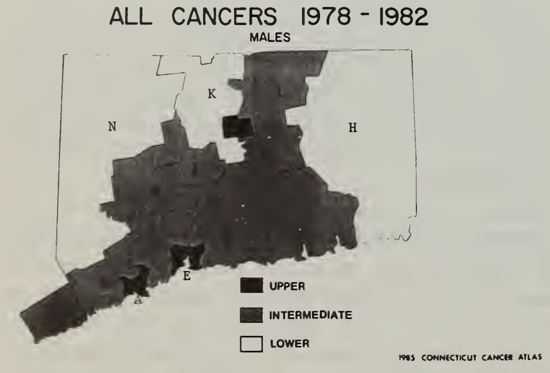

Figure 1

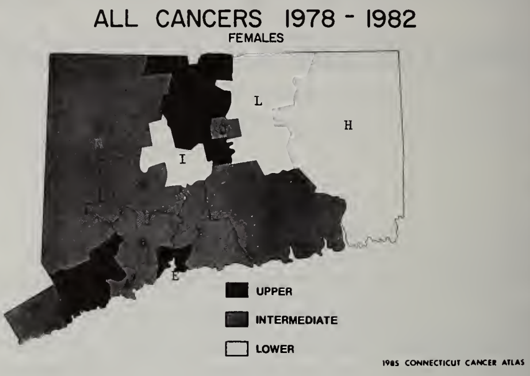

Figure 2

Table 1
INCIDENCE OF ALL CANCERS COMBINED (AVERAGE ANNUAL RATES PER 100,000 POPULATION AGE-ADJUSTED TO THE 1970 US STANDARD MILLION), CONNECTICUT, 1958-1982

	1958-62	*1963-67*	*1968-72*	*1973-77*	*1978-82*
			MALES		
State	329.6	347.9	369.6	393.3	412.8
AREA					
A	355.1[1]	372.0[1]	419.7[1]	425.5[1]	452.2[1]
B	301.2[2]	333.3	341.1[2]	386.7	403.6
C	309.8[2]	341.6	361.5	405.0	407.2
D	326.7	344.0	352.1	387.4	415.8
E	350.2[1]	376.5[1]	378.3	433.7[1]	450.4[1]
F	344.8	362.8	379.3	383.4	405.8
G	317.0	335.8	356.4	384.8	428.7
H	289.2[2]	292.1[2]	333.7[2]	356.2[2]	387.6[2]
I	343.7	364.7	374.9	388.1	400.4
J	353.7[1]	389.3[1]	422.9[1]	441.2[1]	457.7[1]
K	292.1[2]	307.2[2]	329.2[2]	355.4[2]	385.0[2]
L	289.9[2]	344.3	354.8	374.2[2]	393.9[2]
M	351.0[1]	341.1	363.1	393.5	406.5
N	306.2[2]	303.9[2]	341.9[2]	360.5[2]	380.1[2]
			FEMALES		
State	275.0	271.9	287.9	316.6	324.8
AREA					
A	283.8	279.6	285.5	311.9	329.7
B	271.4	266.0	286.2	326.5	333.2
C	268.9	271.1	303.1[1]	330.9[1]	319.6
D	281.0	257.3[2]	284.6	323.6	317.0
E	286.9	288.1[1]	290.8	320.3	343.7[1]
F	248.6[2]	284.5	285.9	316.2	319.5
G	256.0[2]	274.8	272.9[2]	316.0	325.9
H	257.5[2]	242.8[2]	265.2[2]	290.3[2]	298.9[2]
I	259.6[2]	252.8[2]	263.9[2]	291.3[2]	311.8
J	283.5	276.3	288.9	295.8[2]	314.3
K	274.6	265.6	295.5	319.1	332.5
L	264.7	256.7	291.8	318.6	312.7
M	256.4[2]	248.0[2]	276.8	305.3	323.4
N	257.0[2]	255.1[2]	263.5[2]	298.9[2]	319.5

[1] Significantly higher than state average ($p < .05$).
[2] Significantly lower than state average ($p < .05$).

Time trends for the state and the sub-areas are presented in the table. Over the 25-year period, male rates in Connecticut increased by 25 percent and female rates by 18 percent. The rise for males has been consistent. The female rate dropped slightly in the early 1960's and then increased. In the late seventies, the rate of increase slowed.

Regional trends are rather distinct for males, but less so for females. The areas with the three highest and three lowest male cancer rates occupied those ranks throughout the last 25 years. All six areas experienced relatively large increases. The smallest increases occurred in three areas of south central Connecticut, F, I, and M. Female cancer incidence shows little regional differences over time. In the south central region, rates tended to be significantly below the state average in the sixties but rose subsequently. The low frequency eastern area (H) is the only one with rates consistently different from the state average.

Remarks: The Connecticut Cancer Atlas is intended to aid in policy making and public health planning for cancer control in the state and to further the efforts of cancer research. The incidence data provided by the Cancer Atlas lay the baseline for continued cancer surveillance and contribute to the development of the total cancer morbidity/mortality picture for the state of Connecticut.

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Cancer in Connecticut Physicians and Lawyers: A Study by Birth Cohorts (1875-1939)

MARY G. MCCREA CURNEN, M.D., DR. P.H., LIVIA R. TURGEON, M.S.,
BARBARA VALANIS, DR. P.H., R.N., MARY LOUISE SKOVRON, DR. P.H.,
ANDRE A.O. VARMA, M.D., M.S. AND JOSEPH L. FLEISS, PH.D.

ABSTRACT—A cohort study of Connecticut physicians and lawyers, born in the years 1875 through 1939, was conducted in order to assess the importance of occupationally related cancers in these two professional groups.

Overall, physicians had significantly higher death rates than lawyers of the same age born in the first four cohorts (1875-1894; 1895-1909; 1910-1919 and 1920-1929) but not in the fifth, most recent cohort (1930-1939). Death rates for cancer were similar in both groups of professionals in all cohorts except in the 1910-1919 cohort where rates for MDs were significantly higher than in lawyers by age 65 ($P < 0.005$).

Death rates for ischemic heart disease (I.H.D.) were significantly higher in MDs in the first 3 cohorts (1875-1919) but declined steadily thereafter in both professional groups, reflecting national trends.

Death rates for suicide/accident increased in the MDs during the first 4 cohorts and stabilized in the fifth, while rates in lawyers declined during this period.

In this study, the overall higher mortality rate in Connecticut physicians as compared to lawyers appeared to be attributable mainly to I.H.D. and suicide/accident, conditions which offer good prospects for prevention.

MARY G. MCCREA CURNEN, M.D., DR. P.H., Clinical Professor of Epidemiology and Pediatrics, Department of Epidemiology and Public Health, Yale University School of Medicine and Yale Comprehensive Cancer Center; Formerly Associate Professor of Public Health (Epidemiology/Cancer Center), Columbia University School of Public Health, New York, NY. LIVIA R. TURGEON, M.S., Research Associate in Biostatistics, Columbia University School of Public Health. BARBARA VALANIS, DR. P.H., R.N., Professor of Nursing; Associate Professor of Environmental Health, University of Cincinnati, OH. MARY LOUISE SKOVRON, DR. P.H., Assistant Professor of Community Medicine, Mount Sinai School of Medicine, New York, NY. ANDRE A.O. VARMA, M.D., M.S., Professor and Chairman, Department of Community and Preventive Medicine, State University of New York at Stony Brook, NY. JOSEPH L. FLEISS, PH.D., Professor and Head, Division of Biostatistics, Columbia School of Public Health.

Introduction

This investigation was carried out to test the hypothesis that physicians may be at an increased risk of dying with cancer because of their exposure to carcinogens in their professional environment. Although known to have been exposed to radiation during medical training and practice, physicians are also likely to have been subjected to other, less well recognized carcinogens in the clinical, hospital or laboratory milieu. For this reason, all MDs licensed to practice in Connecticut from January 1, 1900 through May 31, 1975 were included in this study, irrespective of their specialty.

In mortality studies of physicians, MDs have usually been compared with the general population. Early cross-sectional studies of mortality among physicians carried out in 1925, 1938-1942 and 1949-1951 used data from the files of the American Medical Association.[1-3] When compared with control populations, physicians had a lower overall mortality and mortality for cancer except for leukemia.[2] Guralnick et al.[4] reported similar results in male physicians in 1950 when compared with male workers from that year's census but did not find an excess of leukemia in physicians. Williams et al.[5] followed through January 1970 cohorts of physicians belonging to the 1923-1924, 1932-1934 and 1942-1944 Harvard Medical School graduating classes and also found that physicians had a better mortality experience than the general population, thus supporting a socio-economic gradient of mortality.

Other investigators, comparing physicians with control populations of white males, have reported that MDs are at an increased risk of dying of diabetes mellitus, coronary heart disease and stroke. They are also at a higher risk of suicide, if under 50 years of age.[1-4, 6-8]

While physicians, in general, have experienced over time a higher risk of leukemia than cancer at other sites when compared to the population at large,[9-14] Lewis[15] noted that radiologists had a significantly higher mortality from multiple myeloma and aplastic anemia than a control population of white males. Court-Brown and Doll[16] studied the mortality of British radiologists over a 60 year period without finding a higher risk for leukemia. Matanoski et al[17] in a 70 year follow-up of U.S. radiologists found that cohorts of radiologists in practice for 40 or more years had an excess risk of cancer mortality 1.5 to 2 times that of other specialists, but no excess of lymphatic and hematopoietic cancers among those who had entered the specialty after 1940.

In addition to radiation, physicians may be exposed over time to a variety of chemicals and anesthetic gases. Many of these are known or suspected carcinogens.[18-22] Physicians are also exposed to infectious agents with potentially carcinogenic properties.[23-24] Vianna et al.[25] reported that among male physicians, Hodgkin's disease was 1.8 times more frequent than in the general male population, 25 years of age and older, who died in New York State from 1960 through 1972. Ho et al., studying nasopharyngeal cancer, found that patients with this disease may constitute a major source of EB virus infection among hospital personnel.[26] In a study of neuroblastoma, Graham-Pole et al. reported higher sensitization to extracts of this tumor among individuals in close, as compared to remote, contact with neuroblastoma patients.[27]

The fact that physicians, in general, have better survival rates than white males of similar age is to be expected since they represent, in the US, at least, a preselected group of individuals, usually from a privileged society, assumed to be in good health when entering medical school and to remain healthy if they continue practicing. By contrast, the general population, selected routinely to serve as a control, is composed of different socio-economic classes and includes individuals whose poor health may have prevented them from joining the work force altogether or for part of their adult life. Studies have shown that in almost every comparison of a single occupational group with the total population, mortality rates are lower in the selected occupational group as a result of this "healthy worker" effect.[28]

Subjects

Because lethal hazards are associated not only with the nature of occupational exposures but also with personal characteristics of individuals adopting these occupations, we compared the mortality experience of physicians with that of lawyers. Members of both professions share similar backgrounds, status, prestige, patterns of personal behavior as well as availability and quality of medical care. They both start their professional education and practice at similar ages and have a comparable way of living as manifested in role performance and life style. By contrast, physicians differ considerably from lawyers in their exposure to potential carcinogens in the professional milieu.

In this investigation, all male physicians and lawyers, licensed to practice medicine or admitted to the bar in Connecticut during a 75 year period (1900-1975), were followed until May 31, 1975 in order to determine who had died and to obtain causes of death and other morbid conditions listed on death certificates. The cumulative probabilities for physicians of dying from all causes, with cancer, and from other selected causes, were compared to those of lawyers for five successive birth cohorts: 1875-1894, 1895-1909, 1910-1919, 1920-1929, and 1930-1939.

Sources of Data

Data were obtained exclusively from existing records. No contact with physicians, lawyers or their families was made at any time.

Physicians

All physicians licensed for the first time to practice medicine in the state of Connecticut between January 1, 1900 and May 31, 1975, were identified through records from the Bureau of Medical Licensure located at the State of Connecticut Health Department in Hartford. Follow-up information was obtained through annual mandatory renewal of the state license. Physicians who failed to renew their Connecticut license in 1975 were followed to see if they had renewed it by 1976. During our study, physicians migrating out-of-state could renew their license without charge, an incentive for maintaining a current Connecticut license even when practicing elsewhere. Identification of deceased physicians by the Bureau of Medical Licensure was practically complete; information on date and place of death and the source of such information was usually available. If not, information leading to the death certificate was obtained from the American Medical Association's obituary listings, its data base on physicians, or from records kept by various medical societies or medical schools' alumni offices. Other sources of information included American medical directories and directories of medical specialists. Death certificates of physicians were readily available from the Connecticut Vital Statistics Division for those who died in Connecticut; they were obtained from state vital statistics departments across the country for those who died out-of-state.

As Table 1 indicates, 11,527 male physicians were included in our analysis. They were predominantly white (99%). Women were excluded because they represented only 6% of the total physician population.

Table 1
NUMBER AND PERCENT OF MDs AND LAWYERS BY VITAL STATUS ON 5/31/75

	MDs		*LAWYERS*	
	No.	*Percent*	*No.*	*Percent*
Total Individuals	11,527	100%	6,334	100%
Alive in 1975	8,924	77.4	4,642	73.3
Lost to Follow-up	233	2.0	401	6.3
Total Deceased	2,370	20.6	1,291	20.4
With Cancer	423		252	
Without Cancer	1,862		915	
Cause Unknown	85		124	

By May 31, 1975, the closing date of the study, 8,924 (77%) physicians were alive and 2,370 (21%) were known to have died; only 2% (233) were lost to follow-up. Death certificates were the only acceptable source for recording causes of and conditions present at death and were obtained for 96% of the deceased. Among them, 423 (18%) died with cancer.

Lawyers

All lawyers admitted to the Connecticut bar between January 1, 1900 and May 31, 1975, were identified through the files of the State of Connecticut Superior Court in Hartford which contained the lawyer's name, date and place of residence when admitted to the bar, last known residence, record or resignation and death when reported.

The Martindale-Hubbell Law Directory[29] was our main source of follow-up. This directory, in existence since the late 1800's, endeavors to list annually, and by state, all living lawyers, whether active or retired, who have been admitted to the bar in the USA and Canada. It is updated annually through the efforts of a network of field representatives working closely with the American Bar Association, the States' Superior Courts, and the many bar associations and law schools' alumni offices across the country. This firm maintains also a nation-wide unpublished alphabetical listing of living and deceased lawyers with date of death when available.

Our study included 6,334 male lawyers. By May 1975, 4,642 (73%) were alive and 1,291 (20%) were known to have died (Table 1). The remaining 401 (6%) were lost to follow-up. Death certificates were reviewed for 90% of the deceased. Among them 252 (19%) died with cancer.

Methods of Analysis

All causes and conditions listed on death certificates of physicians and lawyers were coded simultaneously for MDs and lawyers by an expert nosologist in conformity with the 8th Revision of the International Classification of Disease (ICD-8).[30] Standardization of diagnostic codes was essential in order to provide uniformity in disease classification over time. This procedure was of particular importance in a study covering three quarters of a century during which major changes occurred in coding rules for the International Classification of Disease.[31] Reliability of coding was checked on a 5% random sample of certificates with less than 1% discrepancy rate between the first and second coding. Because death *with* cancer and not *of* cancer was the end point in this study, all diseases and morbid conditions listed on death certificates were coded, irrespective of whether or not they were entered as the underlying cause of death. Death with cancer included all primary and secondary malignant neoplasms.

Birth cohorts were constructed so that each individual entered into the analysis at the time of his Connecticut licensure (MD) or admission to the Connecticut bar (lawyer). The minimum age at entry was 25 years. Each member of a cohort was considered as being at risk for half a year in the year in which he first entered and for a similar period in the year in which he was lost to follow-up. Individuals were considered lost to follow-up in the year when they were last known to be alive during the study period.

For each of the 5 birth cohorts indicated above, age-specific mortality rates within five year age categories were computed by the modified life table method.[32]

Conditional probabilities of dying within 5 year intervals were obtained by dividing the number of deaths within the age category by the number of persons effectively exposed to the risk of dying during the interval. Individuals at risk of dying in a given interval included those who were present during the entire 5 year interval as well as the fractional contribution of those who entered or withdrew at ages falling within the 5 year interval. For example, an individual present for 3 years of a five year

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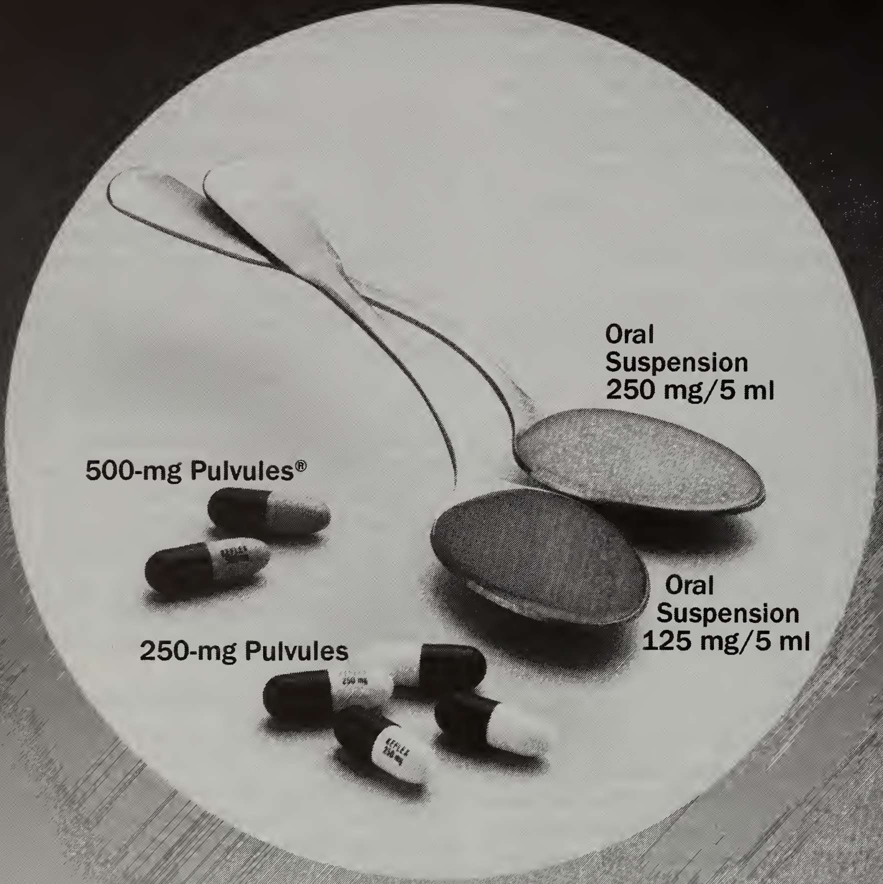

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interval, contributed only 3/5 exposure time to the denominator of that interval. Individuals were withdrawn from the life table analysis within a 5 year age interval if they were either alive and still observable at the closing date of the study (May 31, 1975), or lost to follow-up during the study period.

The cumulative probability of survival from age 25 to any given age was obtained by successively multiplying the proportion surviving each 5 years interval. Thus successive cumulative survival values and their complements, the cumulative probabilities of dying, (Qx's), by the indicated age x, were computed for each birth cohort and professional group. The latter (Qx's) were plotted.

The survival experiences of the two professional groups for each of the birth cohorts were compared and evaluated by dividing the observed difference in survival by the standard error of the difference, and referring the critical ratio to the standard normal distribution.[33] The variance estimation was based on Greenwood's formula.[34] A computer program was written to accommodate this special type of modified life table technique where the input data have variable entry points and where there is censoring on the right.

In order to confirm the consistency of our data with previous reports, the mortality experience of Connecticut physicians and lawyers was compared to that of US white males. As US data are only available for the birth cohorts of 1899-1903, 1908-1912, 1918-1922 and 1928-1932,[35] we grouped, for this particular analysis, MDs and lawyers according to these selected birth years. In Figure 1, ages are plotted on the abscissa and limited at the upper end by the last age category which an individual could have reached by the end of the study period (i.e., incomplete cohorts). On the ordinate, the cumulative probabilities of death are plotted on a logarithmic scale and represent the number of deaths from all causes by a given age x, out of 1,000 persons at risk. As expected, our data illustrate that, in Connecticut, both physicians and lawyers have better mortality experiences than the U.S. general population. This was true for all four birth periods selected for this investigation.

Results

A. Death from all causes

MDs had a higher mortality risk from all causes than lawyers in all five birth cohorts. This can be seen in Figure 2a which illustrates the trends in cumulative risk of dying from all causes by indicated age for successive birth cohorts of MDs and lawyers. Table 2 indicates that these observed differences were statistically significant for the four earlier cohorts (for those born before 1930) at the $P<0.05$ level for 3 cohorts and at the $P<0.01$ level for the birth cohort of 1910-1919. Furthermore, the significant differentials occurred at successively younger ages for each consecutive cohort. MDs had a significantly higher cumulative probability of dying from all causes than lawyers by age 85 in the 1875-1894 birth cohort, by age 75 in the 1895-1909 cohort, by age 65 in the 1910-1919 cohort and by age 55 in the birth cohort of 1910-1929. For the groups born between 1930 and 1939,

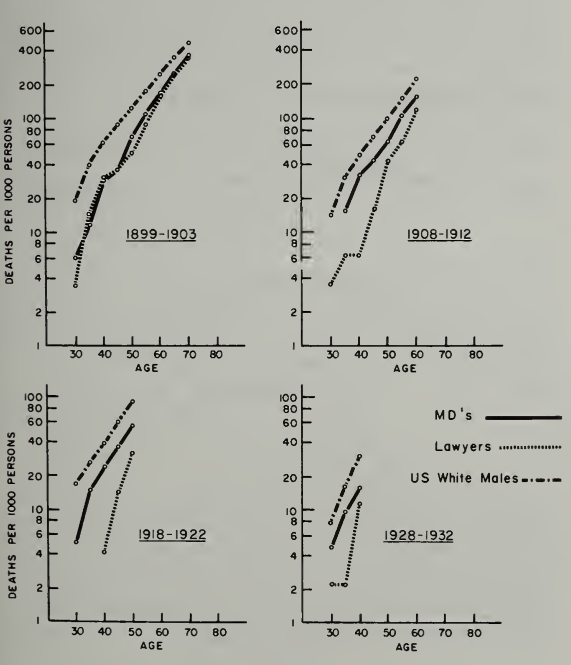

Figure 1
Cumulative risk of dying (from age 25 yrs.) from ALL CAUSES, by indicated age, for selected birth cohorts of U.S. white males and corresponding cohorts of Connecticut MDs and lawyers.

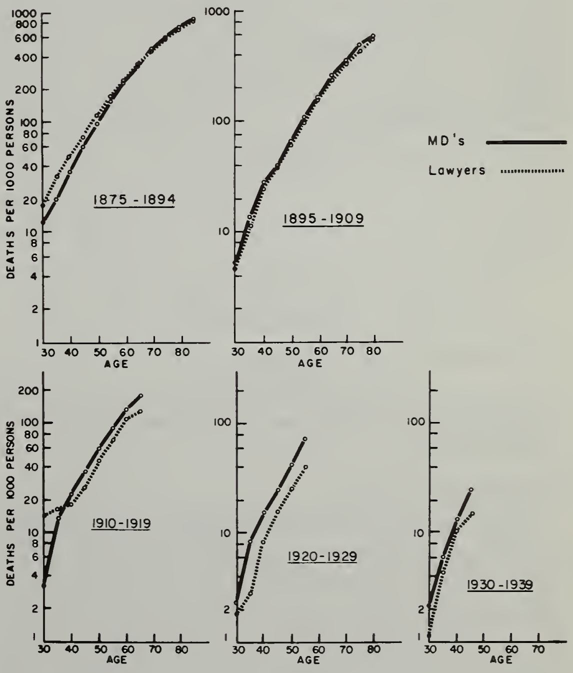

Figure 2a
Cumulative risk of dying (from age 25 yrs.) from ALL CAUSES, by indicated age, for successive birth cohorts of MDs and lawyers.

rates could only be computed through age 45, 24.4/1000 for MDs versus 14.4/1000 for lawyers and were not significantly different.

Table 2
CUMULATIVE RISK OF DYING FROM ALL CAUSES AND FROM SPECIFIC CAUSES OF DEATH IN BIRTH COHORTS OF MDs AND LAWYERS

Birth Cohorts	*Deaths*			
	Total	*Cancer*	*I.H.D.*	*Suicide/ Accident*
1875-1894	MD>L*		MD>L*	MD>L
1895-1909	MD>L*		MD>L*	MD>L**
1910-1919	MD>L**	MD>L***	MD>L**	MD>L
1920-1929	MD>L*			MD>L**
1930-1939	MD>L			MD>L*

$^*P<0.05$ $^{**}P<0.01$ $^{***}P<0.005$

Trends in the cumulative probabilities of death by ages 45, 55, 65 and 75 for successive birth cohorts of MDs and lawyers are illustrated in Figure 2b. As in the general US population, death rates declined over time for each age category and professional group considered. It is noteworthy, however, that starting with the 1910-1919 birth cohort, death rates in lawyers appear to be falling more rapidly than in MDs. The more recent cohorts have not aged enough to determine whether this difference will persist and increase further with time.

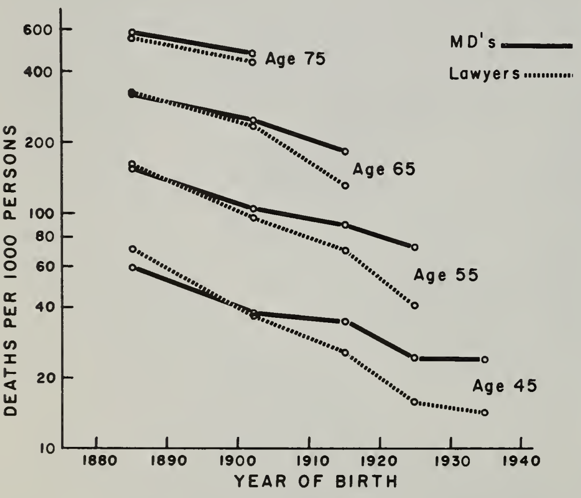

Figure 2b
Trends in the cumulative probabilities of death (from age 25 yrs.) from ALL CAUSES by ages 45, 55, 65 and 75 yrs. for successive birth cohorts of MDs and lawyers.

B. Death with cancer

Cumulative probabilities of death with cancer for MDs and lawyers fluctuated within close ranges prior to the cohort of 1910-1919 as seen in Figure 3a. However, for individuals born in the decade of 1910-1919, rates by age 65 were significantly higher ($P<0.005$) for physicians than for lawyers as indicated in Table 2. Physicians continued to manifest higher rates than lawyers in subsequent birth cohorts but these differences did not reach significance by the end of the study.

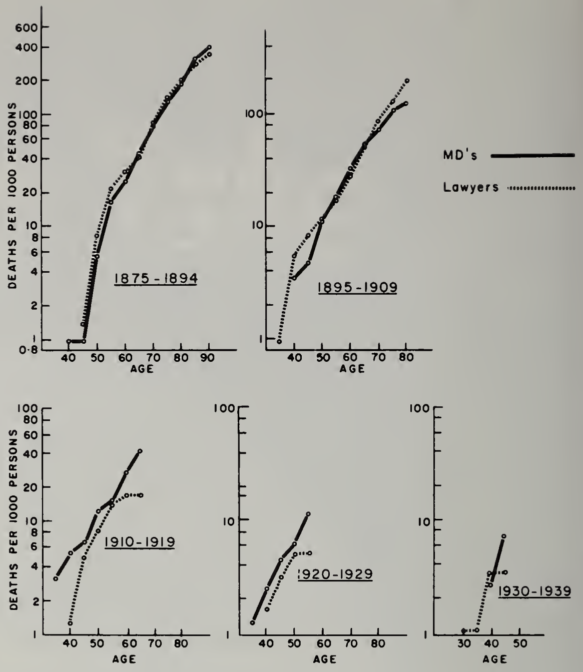

Figure 3a
Cumulative risk of dying (from age 25 yrs.) with CANCER, by indicated age, for successive birth cohorts of MDs and lawyers.

Figure 3b illustrates trends in cumulative probabilities of death with cancer by ages 45, 55 and 65 for successive birth cohorts of MDs and lawyers. A marked decline in rates among both groups of professionals born from 1910 through 1929 is apparent. In the most recent cohort of 1930-1939 however, this trend is reversed by age 45, with an upturn in rates in both groups, those for lawyers paralleling MDs's but at a lower level.

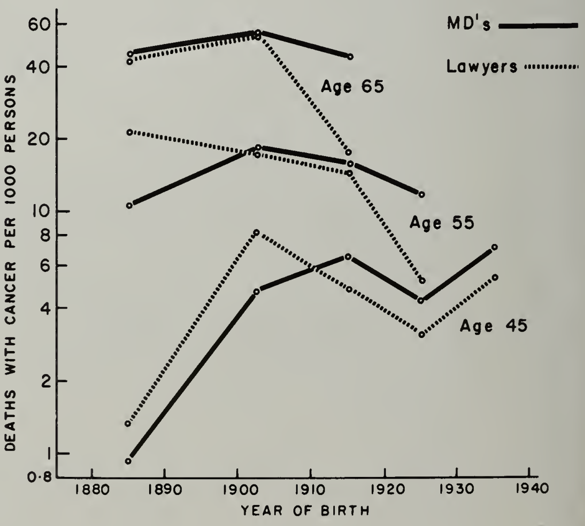

Figure 3b
Trends in the cumulative probabilities of death (from age 25 yrs.) with CANCER by ages 45, 55 and 65 yrs. for successive birth cohorts of MDs and lawyers.

C. Site specific cancer death

MDs manifested considerably higher rates than lawyers for lymphatic and hematopoietic cancers in 2 cohorts, namely 1910-1919 and 1920-1929. This difference was significant for the 1910-1919 cohort only, with cumulative probability of death by age 65 of 10.2/1000 for MDs (12 deaths) and 2.4/1000 for lawyers (2 deaths). In this cohort, approximately 26% of all deaths with cancer in MDs and 14% in lawyers were lymphatic and hematopoietic cancers. Among physicians, they included 4 cases of Hodgkin's, 2 lymphosarcoma, 1 giant follicular lymphoma, 1 multiple myeloma and 4 leukemia. In lawyers, 1 case of Hodgkin's disease and 1 of reticulum cell sarcoma were found.

The small number of radiologists in our study precluded a comparison of their mortality experience with that of nonradiologists. Very few physicians, in those years, indicated radiology as a specialty on renewing their annual Connecticut license.

D. Other causes of death

Cumulative probabilities of death were computed also for ischemic heart disease (I.H.D.) and for suicide/accident as these were among the most frequently encountered conditions listed on death certificates in our study.

1. Ischemic heart disease

As indicated in Table 2, death rates for I.H.D. were significantly higher in MDs than in lawyers in each of the first 3 cohorts and this increase was already manifest by age 45 in the 1910-1919 cohort. However, death rates for I.H.D. have, in general, steadily declined over time in both groups of professionals.

2. Suicide/accident

These have been combined under a single rubric, since two thirds of the accidents reported at death could have been suicides (e.g. barbiturate poisoning, undetermined whether accident or suicide). Rates in MDs increased in the first 4 cohorts and stabilized in the fifth, while rates in lawyers declined throughout this period.

Significant differences were found in three cohorts: 1895-1909, 1920-1929 and 1930-1939 as indicated in Table 2. It is noteworthy that MDs already had significantly higher rates of suicide/accident than lawyers by age 45 in the two most recent cohorts (1920-1929; 1930-1939).

Discussion

In order to investigate whether there was a marked difference in the age at which MDs and lawyers entered the study, the cumulative probabilities of death from all causes were computed only for MDs and lawyers who entered the life table between ages 25 and 34. The results of this analysis were very similar to those found above, where age at entry was uncontrolled.

Although the overall percent of individuals lost to follow-up among physicians (2%) and lawyers (6%) varied by birth cohort, the likelihood that this difference may have influenced markedly our results is remote. This was tested in subsequent studies where we were unable to demonstrate that these differences in lost to follow-up had a significant impact on our results.

It is not surprising that lawyers were more difficult to follow-up than physicians as they are not required by law to renew their license annually. They frequently leave the bar in the course of their career to undertake positions unrelated to their previous bar activities.

We have no reason to believe that, in our study, the unavailability of a small number of death certificates was, in any way, related to cause of death. The majority of death certificates had listed two or less causes of death. The median number of causes entered on certificates from the two earlier cohorts was 2.64 for MDs and 2.63 for lawyers, and from the two later cohorts 2.13 and 2.27 respectively. There is therefore no evidence to suggest that death certificates of MDs were more complete than those of lawyers.

Results of cross-sectional mortality studies, are not comparable to those obtained through cohort studies. In the former, the analysis reflects the life experience of those who died at a particular time in history, regardless of their birth year. In the later, individuals are followed through life while sharing experiences and aging together.

It should be emphasized that this study was designed to assess the importance of occupationally related cancers in two comparable professional groups, doctors and lawyers, and was not intended to explore the relative risk of cancer in various medical specialties. The latter has been done previously and is complicated by the fact that, in the course of a lifetime, many physicians may practice in more than a single specialty. Moreover, in this investigation, as in others of limited population size, those physicians who did remain in one field throughout their career were too few in number for a separate analysis of the data by medical specialty. Thus, in this study, the mortality experience of physicians was compared with that of lawyers from the same state who share, with physicians, similar life-style and socio-economic status. Our results are summarized in Table 2.

During the 75 years of this study, physicians have consistently died at a younger age than lawyers and this trend has increased for MDs born after 1910.

Although cancer rates were higher in MDs than in lawyers born in 1910 and thereafter, the difference only reached significance for the 1910-1919 birth cohort of physicians and lawyers who must have graduated from medical and law schools between 1935-1944 which included the World War II period. At that time, physicians were likely to have been exposed to radiation hazards and to other factors, such as overcrowding and infections prevalent during war times. The finding that cancers of the lymphatic and hematopoietic systems, including Hodgkin's disease, accounted for significantly higher cancer rates in MDs than in lawyers in the 1910-1919 birth cohort supports Vianna et al.'s report of high rates of

Hodgkin's disease among physicians in N.Y. State born predominantly during the 1911-1923 period.[25]

Stress, as a factor in the cause of coronary heart disease, mental illness and suicide among MDs and lawyers, has usually been studied by comparing its effect on individuals practicing different specialties within these two professional groups and not, as in this study, between members of these two professions considered as a whole. Russek[36] reported a striking association between the prevalence of coronary heart disease and the relative stressfulness of occupational activity in a study of 1,837 physicians and 1,292 lawyers, aged 40 to 69, from North America. Physicians were grouped according to a prejudged scale of stressfulness in 4 specialties. These were ranked by increasing stress as follows: dermatology, pathology, anesthesiology and general practice. The specialties of lawyers were similarly ranked by increasing stressfulness: patent law, other specialties, trial law and general law practice. The finding, in each age group, of an increasing prevalence rate of coronary heart disease with advancing stress, was highly significant. All data were obtained through a mailed questionnaire. The age-adjusted percentage prevalence of coronary heart disease for all physicians in the study was 8.1%, while the corresponding percentage for all lawyers, was 6.7%. In our mortality study, physicians born in the three earlier cohorts manifested significantly higher rates for I.H.D. than lawyers (Table 2), thus supporting Russek's findings. In a later paper,[37] this author discusses the possibility that smoking may be related to coronary heart disease through an emotional stress mechanism. Unfortunately our study does not provide data on smoking.

Rates on suicide/accident were significantly higher in MDs than in lawyers in 3 of the 5 birth cohorts included in our study. Although physicians in general enjoy a longer survival than the population at large, their rate of behavioral disturbances, divorces, substance abuse and mental illness, notably depression and suicide have been reported greater than in other groups of similar socioeconomic status.[38] Other investigators have not confirmed these observations.[39]

In conclusion, more physicians born in successive cohorts died at younger ages than lawyers and this excess in mortality rates, except for the most recent cohort, was significant throughout the study. Differences in mortality rates for cancer between the two groups were not appreciable except for the cohort of 1910-1919 when physicians had an excess of lymphatic and hematopoietic cancers, including leukemia and Hodgkin's disease. It is unlikely that radiation alone accounted for this finding.

In our study, the overall higher mortality rates in physicians as compared to lawyers appeared to be attributable mainly to I.H.D. and suicide/accident, conditions which offer encouraging prospects for application of preventive measures.

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The Tumor Registrar: Past, Present, Future

MARILYN C. HURST, M.S.

ABSTRACT—The National Tumor Registrars Association, Inc. (NTRA) was founded in 1974 for the purpose of providing quality educational programs for its members. The certification examination for tumor registrars was developed by NTRA in 1983 to measure tumor registrar competency. The Tumor Registrars Association of Connecticut, Inc. (TRAC), founded in 1976, offers educational programs of particular interest to Connecticut tumor registrars. The certified tumor registrar (CTR) is capable of performing a wide variety of cancer data management skills.

Two major problems effecting the future of tumor registries are funding and the Prospective Payment System (PPS) which was implemented in October, 1983. Because of the PPS, new uses of tumor registry data have been identified. The tumor registrar's expertise in cancer data abstraction and staging can be a valuable resource in improving the accuracy of DRG assignments. Increased cancer data utilization and the acceptance of the tumor registrar's role in the PPS will insure the future existance of tumor registries.

Credible data are the foundation of any statistical analysis no matter how sophisticated. A few tumor registry clerks or secretaries as they were called in the 1930's through the 1960's, recognized the importance of this fact and spent considerable time educating themselves to be sure the cancer data they abstracted were accurate and complete. The education resulted from studying borrowed medical text books and from conferring with interested physicians. Formal training programs for tumor registrars were few, of short duration, and expensive in the early years.

In the 1960's, the Tumor Registry Training Program, under the direction of Dr. Calvin Zippin, was established at the Cancer Research Institute of the University of California in San Francisco. Today the program has grown such that training is offered to personnel of cancer patient data systems as well as tumor registries. The California tumor registrars were the earliest graduates and one of the first groups to organize regional associations

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MARILYN C. HURST, M.S., CTR, Past President of Tumor Registrars Association of Connecticut, Inc. and The National Tumor Registrars Association, Inc.; Associate Director for Data Management, Clinical Information Services, Yale-New Haven Hospital, New Haven, CT.

for the purpose of continuing their education.

In 1956, the American College of Surgeons Commission on Cancer set standards for hospital tumor registries which had to be met for hospital cancer program accreditation.[1] In 1972, the Surveillance, Epidemiology, and End Results (SEER) Program was established as an outgrowth of the End Results Program[2] and the National Cancer Surveys.[3-5] Existing population based registries of known quality entered the SEER Program in 1972. Others of particular epidemiological interest were established later.[6] Of prime importance to these programs was the availability of trained tumor registrars.

In the program announcement for a Cancer Registry Symposium to be held in San Francisco March 13-24, 1972, March 16 was the day designated for the First National Meeting of Tumor Registrars. Sponsors of this meeting were the Cancer Research Institute Tumor Registry Training Staff, the California Tumor Registry, the California Division of the American Cancer Society, the Commission on Cancer of the American College of Surgeons, and the California Regional Medical Program Area I. Hosts were the Northern and Southern California Tumor Registrars Associations. Well over two hundred health care enthusiasts attended the meeting. A seven member ad hoc committee of tumor registrars was appointed to determine the feasibility of establishing a national association.

Two years later, on March 14, 1974 in Dallas, Texas, the National Tumor Registrars Association (NTRA) was founded and consisted of 113 members representing twenty-eight states and the District of Columbia. The primary purpose of the NTRA as stated in the bylaws adopted at this meeting is, "To promote research and education in Tumor Registry administration and practice so that we may be of greater service to the cancer patient."[7] R.R. Richardson, chairman of the ad hoc committee, was elected as NTRA's first president. The concept of the tumor registrar as a health care professional was slow in acceptance during the early growth of the Association. Very few understood what was involved in establishing and maintaining a viable tumor registry.

Originally, tumor registries only existed in hospitals where physicians had a special interest in oncology. One of the first can be traced back to the eighteenth century in London. Sir Percivall Pott identified the relationship between scrotal cancer and chimney sweeps in a 1775 publication based on cancer data collected as far back as 1728.[8] So the first tumor registrars were physicians. They carefully abstracted pertinent data and followed their patients regularly. The tumor registry secretaries typed these records and made the appointments for patients due for follow-up examinations. As more became known about cancer and as better diagnostic tests were developed, the cancer data base had to be expanded and more patients required follow-up. The physicians no longer had the time necessary to continue their registries. Many abandoned them but others found that the secretary, soon to become the tumor registrar, had been learning through the process and much of the activity could be delegated. Always, however, at least one physician realized the importance of informing the tumor registrar of new advances and of constantly monitoring the quality of data abstracted.

Connecticut has the distinction of having the oldest hospital based tumor registry established at Yale-New Haven Hospital in 1921 with complete cancer reporting in 1926. Furthermore, the Connecticut Tumor Registry is the oldest population based registry in the United States having been established in 1935. It is also one of the original SEER registries. For these registries to have been in continuous operation since their inception demonstrates the strong commitment Connecticut physicians have made for almost sixty years at Yale-New Haven and for fifty years throughout the state. Key support from the Connecticut Division of the American Cancer Society, the SEER Program of the National Cancer Institute, the Connecticut State Medical Society Cancer Coordinating Committee, and more recently from the American College of Surgeons and the Comprehensive Cancer Center of the Yale University School of Medicine has also played a significant role in the continuity of cancer data in our state.

Once the NTRA was founded, older state and regional associations in the District of Columbia, Michigan, Illinois, Ohio, Pennsylvania, California and the state of Washington strengthened and new ones emerged. In September 1975, the first formal workshop for Connecticut hospital tumor registrars was held at the University of Connecticut Health Center in Farmington. In addition to the Center, sponsors included the Connecticut Health Department, the American College of Surgeons, and the American Cancer Society: Connecticut Division. Faculty were Connecticut physicians and staff members of the American College of Surgeons Commission on Cancer and the SEER Program of the National Cancer Institute the latter being NTRA members. During the three day workshop, the tumor registrars were encouraged to join the NTRA and to develop their own state association. As a result of the enthusiastic response, an organizational meeting was held on February 25, 1976. John T. Flannery, now Chief of the Connecticut Tumor Registry, chaired the meeting of nineteen tumor registrars. Charlotte Piggott of the University of Connecticut Health Center was elected the first president of the Tumor Registrars Association of Connecticut (TRAC). Within a year, TRAC adopted bylaws, applied for incorporation, and was sponsoring quality educational seminars on a regular basis.

As the national and state associations grew in membership and strength, the priority for both was to establish a process to measure tumor registrar competency. Salaries were low and acceptance of the tumor registrar as a health care professional was still limited. In fact, many registrars were required to take vacation time and pay their own expenses when attending educational functions. Even an accredited hospital cancer program by the American College of Surgeons did not guarantee a qualified and well trained tumor registrar. Frequently, an interested physician or the Cancer Committee was responsible for meeting the requirements for an approved registry.

In response to this need, the NTRA published the *National Tumor Registrars Association Educational Standards* in 1978 and a revision in 1983. The seven modules are:

I. Introduction to Cancer and Management of the Cancer Patient
IIA. Organization and Operation of a Tumor Registry
IIB. Medical Records
III. Role of the Tumor Registrar in the Health Care Delivery System
IV. Epidemiology
V. Biostatistics
VI. Computerization of Tumor Registry Data
VII. Residency Requirements

The modules assume college level completion of courses in basic human anatomy, physiology, medical terminology, mathematics, statistics, computer science, and managerial skills. In addition, a job description was developed as a guide for hospital administrators and others involved in hiring tumor registrars. The American College of Surgeons has included this job description in its *Cancer Program Manual: A Supplement on the Tumor Registry.*

Once the educational standards were established, work began on developing the certification examination. The official training manuals are the *Self Instructional Manuals for Tumor Registrars* of the SEER Program. The concept of the manuals was originally conceived by C. Dennis Fink, Ph.D., and Robert F. Ryan, M.D. for the Louisiana Regional Medical Program.[9] Field testing began in 1977. Requests for more educational opportunities grew for most of the tumor registrars had learned on the job and few had attended college. TRAC was fortunate to receive an educational grant from the Comprehensive Cancer Center at Yale. In 1980, the Eastern Area Tumor Registry Training Program was developed and implemented by TRAC, the American Cancer Society: Connecticut Division, the Comprehensive Cancer Center at Yale, and the Connecticut State Medical Society. Sponsors included the American College of Surgeons, the Connecticut State Department of Health Services, the University of Connecticut Health Center, and Meriden-Wallingford Hospital. The program took place over a ten month period and has been shared with other state associations. NTRA established a program recognition and endorsement process to assist its members in selecting quality educational opportunities. The first certification examination was offered on March 12, 1983 throughout the United States. 543 certified tumor registrars (CTR) were honored at the Ninth NTRA Annual Meeting held at Yale University. The number now exceeds 800. To maintain certification, the tumor registrar must meet the requirements of the NTRA Continuing Education Program.

Today, NTRA has more than 1000 members representing all fifty states, Canada, and Portugal. It has been recognized by the American College of Surgeons, Abdominal Surgeons, Chest Surgeons, Colorectal Surgeons, Obstetricians and Gynecologists, Pathology, Radiology, and the American Cancer Society. NTRA has been represented on the Commission on Cancer of the American College of Surgeons since 1977 when Vida Peterson became the first non-physician member. Acceptance as a health care professional has been achieved. However, new challenges have evolved.

Funding of tumor registries has been greatly reduced in recent years. Traditionally, the main function of most registries was to collect complete, accurate data. Then the data were to be used for the purpose of learning more about cancer and for improving the quality of patient care. Funding agencies found that cancer data utilization was frequently minimal such that the expense of data collection could not be justified.

The certified tumor registrar is capable of performing a variety of cancer data management functions in addition to data gathering. However, more time must pass before funding agencies can assess the full impact of certification on tumor registry productivity. The concern that funds allocated for data collection without demonstrable data utilization is real. One solution to the problem involves an analysis of the tumor registry using management engineering techniques. The efficient development of a tumor registry must be based on a strategic plan which includes data retrieval for specifically designated purposes. The uses should be determined before the data base and collection methods are established. If the registry is computerized, adequate funding for data retrieval programming and computer time must be an integral part of the plan. Also required for proper cancer data utilization is strong support of the strategic plan by physicians, researchers, and hospital administrators.

Since 1982, NTRA has published an annual call for papers using registry data. After a selection process, the papers are presented at NTRA annual meetings. This activity has provided an opportunity for other tumor registrars to learn how to develop meaningful reports in order to generate more interest in cancer data utilization in their hospitals. If the use of cancer data does not increase, funding will be reduced further and the future of tumor registries may be in jeopardy.

Another major challenge is the implementation of the Prospective Payment System (PPS) for reimbursement of Medicare inpatient hospital expenses as of October 1, 1983.[10] The PPS adopted is based on diagnosis related groups (DRGs) which were developed at Yale.[11] DRGs have revolutionized hospital operations. In the past, few questioned rising hospital costs because the primary goal was the delivery of quality patient care. The goal has not changed, however, hospitals have had to scrutinize costs in relation to efficacy of services provided.

Hospital administrations are focussing on direct patient care. Data collected in a tumor registry today benefit the cancer patients admitted in the future. Most hospitals fund tumor registry operations and adverse effects are already being felt. Some registries have closed and others have experienced staffing reductions. The knowledgeable tumor registrar can be an asset in relation to DRG assignment of cancer patient admissions. Severity of illness is not measured accurately by DRGs in relation to reimbursement. For example, the DRG assignment for a patient first diagnosed with microinvasive cancer of the cervix is the same as that for a patient first diagnosed with cancer of the cervix with distant metastases. Both patients are the same age and have had identical major surgery. The first patient also had a urinary tract infection. The resources required for each patient differ substantially. Efforts to establish a severity of illness measure are being made. For cancer patients, stage of disease will definitely be a factor.

Today, the tumor registrar is a valuable resource person in determining the primary site accurately which can result in large differences in reimbursement. In the future, knowledge and expertise in cancer staging systems will be required to guarantee appropriate PPS reimbursement. NTRA and TRAC have recognized the emerging role of the tumor registrar in the PPS. Since 1983 educational sessions on DRGs have been offered. Registrars are encouraged to inform hospital administrators of their expertise and their understanding of DRGs.

Funding and the PPS have had adverse effects on tumor registries. However, implicit in both are alternatives which can insure the future existance of tumor registries. New uses of tumor registry data in relation to PPS will result in improved funding of tumor registries. The application of the tumor registrar's expertise will result in increased accuracy of DRG assignments.

The roles of all health care professionals are changing because of the Prospective Payment System. The important role of the tumor registrar is clear. How well the new aspects of this role are accepted will significantly effect the future existance of tumor registries.

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The Impact of the Connecticut Tumor Registry on Cancer Epidemiology

J. WISTER MEIGS, M.D.

What would cancer epidemiology be like in the United States without U.S. census data to provide national, state and local demographic data for reliable denominators? We can ask a similar question for numerator information if we substitute Connecticut Tumor Registry (CTR) for the census. About 60 years ago, physicians and civic and business leaders in New Haven became concerned because there was no source for comprehensive, systematic, ongoing, high quality information about the incidence of cancer and survival of patients in New Haven, despite an impression that many forms of the disease were becoming more common.[1] The Connecticut State Medical Society and the State Department of Health, supported by the Connecticut Division of the American Cancer Society, persuaded the legislature in 1935 to pass the law that authorized what is now the oldest population-based registry in the world.

When CTR was the only U.S. population-based registry, its data served as a U.S. standard for numerator figures that could be combined with census denominators to give cancer incidence, survival and mortality rates for this country. It has been used from its earliest existence as a model for new registries in other states and areas in the U.S. and elsewhere. Other U.S. registries now provide numerator data to complement those from Connecticut and represent the diversity of the total population.

It would be impractical, and would make dull reading, to try to document all the uses of CTR as a resource for epidemiologists and other scientists in studies of malignant disease. We have lists that include about 400 publications in the scientific literature, but they cover only a few of the multiple uses of CTR data for reference purposes. This brief review will give examples of classes of studies based on CTR. Many selections are made from research done in the State by workers who used not only CTR but also other records available within Connecticut. Categories include: (1) National and international uses of the basic data on incidence and survival; (2) Uses of the registry's data quality control methods in efforts to improve cancer management and control; (3) Clinically oriented studies that take advantage of the population-based data to give broadly applicable information, especially about rare types of cancer; (4) Case-control studies that require ascertainment of all persons in a defined geographical area to assure results that can be generalized; (5) Exploratory studies of environmental risk factors and interactions of socio economic, occupational, geographical, genetic, communicable and other disease factors in cancer incidence; (6) Cohort studies that require unbiased cancer ascertainment among all residents of a defined geographical area over long time periods.

Many CTR studies have been strengthened by the use of other statewide data sources that could be linked with CTR records, e.g. deaths, births, marriages, communicable diseases, licences for operation of motor vehicles, practice of medicine, nursing, cosmetology, law, city directories of residence and occupation, drinking water supply records, industrial hygiene survey records of state inspections of factories.

The world wide stature of CTR is indicated by the first volume of Cancer Incidence in Five Continents, a publication of the International Union Against Cancer in 1966, edited by Richard Doll. United States cancer incidence was presented only for the state of Connecticut, and New York state excluding New York City.[2] CTR data were rightly regarded at that time as the best available standard for the U.S.[3] About 30 registries provided information to this publication.

With the establishment of the International Agency for Research on Cancer (IARC) and the International Association of Cancer Registries (IACR) a few years later, publication has been continued by IARC. Volume IV of the compendium is sponsored also by the World Health Organization. By 1982, there were data from over 80 population-based cancer registries, now located in most large and many small countries.[4] The U.S. section of

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J. WISTER MEIGS, M.D., Clinical Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine.

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Volume IV includes data from 9 population-based registries in addition to Connecticut and New York. These more recent registries are, like Connecticut, part of the Surveillance, Epidemiology and End Results (SEER) network established by the National Cancer Institute (NCI) in 1973 to expand the work of NCI's End Results Group (ERG) that took data from Connecticut and other then-existing registries to compile information on survival from cancer for national and international use. An illustration of this use is Cancer Patient Survival Report No. 5.[5]

The SEER network has used CTR data in scores of publications in cancer epidemiology. An impressive example of this was NCI Monograph 57 with detailed tables of both incidence and mortality data from Connecticut and other SEER registries for 1973-77.[6]

The foregoing illustrations are concerned with basic reference uses of CTR. They will be complemented by publication of another NCI Monograph, prepared by Heston et al, from Yale and the CTR, and providing detailed tables of cancer incidence in Connecticut by 5 year age groups and 5 year time periods from 1935-1979. This provides the longest detailed historical record of cancer incidence in the world.[7] It is one of many epidemiology research products that have grown from the creation in 1973 of a research arm for CTR in the form of the Connecticut Cancer Epidemiology Unit (CCEU).[8]

The CCEU came to exist because of widespread recognition that CTR resources were underutilized for research purposes. The staff of the CTR and the State Department of Health could produce reliable data on cancer incidence, survival and mortality on a regular schedule but could undertake only a few of the important research projects that this basic information made possible. In the early 1970's discussions among the agencies that had originally sponsored CTR, namely the State Medical Society, the Cancer Society and the Health Department were augmented by Yale and University of Connecticut faculty and representatives of NCI who were involved in federal support of CTR. It is noteworthy that several NCI epidemiologists, especially William Haenszel and Sidney Cutler had become aware of the research potential of CTR while they were on the staff of the Connecticut Department of Health. An important contribution of CTR to cancer research has been to give training and experience to both staff and visiting students and scientists who have carried knowledge of CTR with them in later work.

Another highlight in the history of CTR's research career was the cooperative effort of staff from CTR and the Norwegian cancer registry to explore similarities and differences of the end results of cancer therapy. A monograph edited by Cutler was published by NCI in 1964.[9] CTR's Henry Eisenberg compared survival from cancer of the large intestine and rectum in Connecticut and Norway as a part of this effort.[10]

The foregoing uses of CTR have been primarily for descriptive epidemiology. Secular trends in cancer incidence, differences in incidence by age or sex or birth cohort were observed directly and inferences were made about possible causes. The effects of treatment were indicated for the population as a whole. Outstanding among the findings of descriptive studies have been the multiple evidences of the carcinogenic effects of tobacco uses. Documentation of the epidemic of lung cancer in Connecticut men associated with cigarette smoking, made it possible to use CTR data to predict a similar outcome among women after their smoking rates rose.[11] Subsequent records of CTR have confirmed this distressing prediction and have convincingly supported efforts by health professionals to deal constructively with this largest of all current environmental health risks.

The most comprehensive recent use of CTR incidence data to explore cancer causes and estimate avoidable risks was made by Doll and Peto in 1981 in a study requested by the U.S. Congress. The accumulated incidence data from 1935-1979 were analyzed in relation to incidence data from other parts of the U.S., as well as U.S. mortality data.[12] The estimates from this study have been taken into account in establishing the national goals for reductions in cancer morbidity and mortality by the year 2000.

A recent study of accumulated CTR records has applied analytic methods to the entire CTR data set from 1940-1979. Mathematical modeling techniques were applied by Roush et al to 25 site data sets.[13] The factors of age, time period and birth cohort could all be considered for each sex. Many leads were developed for further study. For example, the malignant melanoma time-trend showed a 40 fold increase in the age adjusted rates for both men and women when birth cohort rates were calculated and used in an age-cohort model. The health and prevention implications of this in relation to current sun-exposure practices will demand attention.

Uses of CTR to improve cancer control in the state started soon after the formal data collection and management program began in 1941. By 1943 it was possible to measure improvements in methods used by hospitals in managing cancer patients. The state legislature had made a grant in 1941 to the Department of Health to be distributed to hospitals in relation to their individual records of numbers of patients served, microscopic specimens examined, diagnostic x-rays, and presence in the hospital record of history, pathological report, follow-up, and information about duration of symptoms or delay in treatment.[14] The CTR reviewed this information and re-imbursed each hospital in accordance with its performance. The high quality of cancer care in Connecticut and the reliability and completeness of CTR data have both been favorably influenced by this program.

Research uses of CTR data were emphasized by Griswold, first chief of the Division of Cancer Research, Connecticut State Department of Health. In 1946 and 1948 he indicated the increase in hospital admissions for cancer, decrease in delays after first symptoms and increased survival that followed implementation of CTR, which had increased education of physicians and hospital staff despite wartime pressures.[15-16]

An early use of CTR records to document geographical differences in cancer incidence and mortality rates and to consider possible explanations, especially methodological or demographic, was reported by Wilder in 1953.[17] This work was extended in 1956 to show that urban industrial areas of the state had experienced significantly higher cancer rates than rural areas. The author noted the importance of search for environmental risk factors to explain these differences.[18]

By the 1950's, CTR had accumulated 15 years experience and there was an increase in studies of specific sites. These clinically oriented reports allowed physicians to learn the characteristics of particular cancers, including their natural history, as they had occurred in the whole population of the state, unbiased by the selection processes that operate when a particular physician or hospital is the source of cases. As examples, Pollack reported on lymphomas,[19] Griswold on cancer of the prostate in children,[20] and Ottenheimer and Oughterson on cancer of the colon and rectum.[21]

The combination of information from CTR with other data collected by or available to the State Department of Health allowed analysis and evaluation of health screening procedures for specific cancers. An early indication of the ineffectiveness of chest x-rays for control of primary lung cancer was given by Greenberg.[22] He reviewed results of over 350,000 chest films taken in Connecticut Tuberculosis Commission programs. The 459 films identified as possible tumor cases were then checked against CTR files as well as death certificates. This comprehensive effort showed that although screening had found significant numbers of previously unsuspected tumors, patient survival had not been improved.

Etiological leads about cancer have also been made with CTR data beginning many years ago. Eisenberg et al demonstrated the existence of genetic factors by showing associations of ABO blood groups and gastric cancer in 1958.[23] Another recurring use of CTR data has been to improve the quality of data collection and reporting by physicians and other health professionals, so that epidemiological studies could become more precise. Bailar and Eisenberg used the combination of CTR records, original hospital charts and death certificates to quantify the precision as well as uncertainties of classifications for uterine tumors not specified as cervical or endometrial in origin.[24] This work has served as a model for other explorations of tumor registry data quality. Concern about environmental risk factors for cancer has increased in recent years, and population-based cancer registries have been used in several national surveys because they minimize biases in case selection.

CTR and other SEER registries provided the basic data and other resources for the National Survey of Environment and Health (NSEH) that addressed the issue of bladder cancer risks from uses of artificial sweeteners. This large case-control study showed the absence of significant association between sweetener use and bladder tumor and has helped put environmental risks in clearer perspective.[25] The Connecticut portion of the study was analyzed separately by Marrett et al.[26] This confirmed the very large contribution of cigarette smoking in causing bladder tumor and indicated a probable risk from excess coffee drinking. Of special interest was the lack of evidence that occupational exposures had caused significant excess bladder tumors in either men or women. This encouraging information would support the view that occupational cancer prevention efforts in the state have had some success.

A case-control study design like that for the NSEH was adopted for The Centers for Disease Control Cancer and Steroid Hormone Study. CTR and CCEU were participants with other SEER registries that interviewed all women aged 20-54 who developed breast cancer over a two year period, as well as comparable numbers of control subjects.[27-29] No excess cancer risks were identified. Thompson analyzed Connecticut data from this study to explore family history of breast cancer as a breast cancer risk factor.[30]

Many of the ways in which CTR information has been used in recent years to help in cancer prevention were outlined by Curnen et al in 1984.[31] This describes CTR capabilities, limitations and accomplishments in case-control and retrospective cohort studies, analysis of multiple primary cancers, benign tumors and precursor lesions, and in surveillance of occupational and other environmental cancer risk factors.

A few examples of CTR based research will illustrate some of these uses. Christine et al showed the relationships of cervical cancer and town socio economic status in 1959-1964.[32] Connelly and Christine combined the communicable disease reporting records of the State Department of Health with those of CTR to explore cancer occurrence after infectious mononucleosis.[33] CTR experience with multiple primary tumors was presented by Schoenberg et al in a monograph.[34] The population-based coverage of CTR was used by Jekel to search for possible impact of allergy extract injections on sarcoma incidence in the upper arm where such injections are usually given.[35]

Studies of rare forms of cancer have used CTR resources to advance understanding of causes and enhance preventive measures. Roush et al[36] identified the presence and persistence of the risk of scrotal cancer among metal workers through occupational exposure to oils. CTR records provided complete, reliable case-finding for the entire state over a 45 year period, and permitted person specific linkages through hospital records, death certificates and city directories to maximize information about histology, treatment, survival and occupation.[37-38] This unique data combination permitted the authors to document the persistence of an occupational risk, the lack of improvement in either early diagnosis, treatment or survival, and the possibility of using scrotal cancer as a marker for other potentially carcinogenic exposures to oils.

Other recent studies that have used research potentials of CTR include a systematic study of mesothelioma by Teta et al.[39] This explored both occupational and nonoccupational associations with asbestos exposure indicators over a 45 year period. It was notable because microscopical slides used to make the original diagnoses were made available by hospital pathologists for most of the cases, even from the 1930's and 40's. Another extensive use of Connecticut's records potential was in a cohort study of cosmetologists by Teta et al.[40] From Connecticut health department licensure records, all names, birthdates and other pertinent data were assembled for over 17,000 cosmetologists from files starting in the 1920's. Vital status was established from these and motor vehicle licence and city directory data. CTR record linkage permitted calculation of observed numbers of cancers, while CTR incidence files provided rates from 1935 forward, for calculations of expected numbers of cancers by site for the entire cohort. No significant excess risks appeared to have been associated with the occupation of cosmetology. A somewhat similar cohort study of nearly 2,000 women who received exogenous estrogens, chiefly diethylstilbestrol, during pregnancy to reduce the risk of abortion, was reported by Hadjimichael et al[41] to estimate risks of breast and other cancers. This work was possible because Connecticut obstetricians and gynecologists requested the study by way of their specialty association and provided their complete office records, extending back to the 1940's, to allow the establishment of cohorts of exposed and nonexposed women who were otherwise comparable. Breast cancer did not occur in significant excess among exposed women.

CTR and other state record resources were used by Farwell and Flannery to show that there was evidence of familial or genetic factors in central nervous system cancers of childhood.[42] This work further illustrated CTR potential for indepth study of all cases of rare cancers.

Finally, CTR records have been used in ecological studies of environmental issues. They take advantage of the town of residence data in CTR and the existence of other town based data for comparisons. Risks to the Connecticut population of asbestos fibers in drinking water were assessed by Meigs et al.[43] In a similar type of study, Walter et al studied possible risks of background terrestrial radiation on Connecticut residents over the 40 years of CTR from 1935-1974.[44] Neither study found evidence of significant risk and each placed the respective environmental risk factor in clearer perspective from the broad public health standpoint.

In summary one can note the wide variety of uses of CTR made to date in epidemiological research and the increasing linkage of CTR records with those from other sources. The potential for further studies is substantial, perhaps especially for carefully designed evaluations of strategies attempted in controlling cancer. With adequate local and national support, CTR can continue to serve the needs of cancer epidemiology into the foreseeable future.

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Strategy for Elimination of Invasive Cervical Cancer in Connecticut

DWIGHT T. JANERICH, D.D.S., M.PH., OLYMPIA HADJIMICHAEL, M.PH.
AND JOHN FLANNERY, B.S.

I. BACKGROUND

Cervical cancer is the only cancer for which there has been long-term and widespread screening. The Papanicolaou (Pap) test, a cytologic method used to detect precursor lesions of the cervix, has contributed to the decreasing incidence and mortality rates. However, a large number of new cases of invasive cancer and cervical cancer deaths still occur annually in the United States.[1,2] There is significant evidence that screening programs have contributed to reducing the rates of invasive cervical cancer both in the United States[3-8] and in other countries where they were used.[9-11] It is not clear whether screening programs for early detection, as they have been used until now, can wipe out this disease. In addition, there are data in recent years showing that invasive cervical cancer rates are increasing among very young women.[12] It is possible, but not at all certain, that these changes may be related to changes in sexual practices in our society during the last two decades.

Several studies suggest that a significant portion of in-

DWIGHT T. JANERICH, D.D.S., M.PH., Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine; Medical Director, Connecticut Tumor Registry, Department of Health Services, Hartford, CT. OLYMPIA HADJIMICHAEL, M.PH., Associate Research Scientist, Department of Epidemiology and Public Health, Yale University School of Medicine. JOHN FLANNERY, B.S., Chief, Connecticut Tumor Registry, Department of Health Services, Hartford.

vasive cervical cancer cases progress in a way that makes it difficult to prevent them with ordinary cervical cancer early detection programs. This small subset of tumors may be biologically and clinically distinct. Laskey, Meigs and Flannery[13] analyzed long-term data from the Connecticut Tumor Registry and concluded that a portion of invasive cervical cancer cases in the State of Connecticut do progress rapidly and may not be preventable by ordinary screening methods. However, it may be possible to identify the biological, clinical and epidemiological characteristics of this sub-group of cases, and to take steps to adjust or improve the screening process to deal with this problem. At least, it may be possible to identify the symptoms associated with this rapidly progressing illness and to make a recommendation to physicians doing routine cervical cancer screening that they alert women to the possibility that certain symptoms will need immediate medical attention when they arise even though the woman has had a recent negative Pap test. A woman who develops rapidly progressing disease after a recent negative Pap test may ignore the symptoms until her condition becomes compelling due to very advanced disease. It appears then, that there is ample need to improve the routine practice of cervical cancer screening.

II. Current Approaches

Although the Pap test is an effective method of detecting early stages of pre-malignant cervical lesions, not all women who are aware of this test make an effort to be screened and even fewer have the test on a repeat basis. Estimates of the number of women screened for cervical cancer in the United States come from several national surveys. From the National Fertility Study[14] conducted in 1970 and the Health Interview Survey[15] conducted in 1973, it was reported that approximately 10% and 21% of the female population respectively had never been screened for cervical cancer. A 1979 survey by the National Center for Health Statistics[16] found this to have changed, with approximately 6% of the women now reporting themselves as never having had a Pap test. In addition, about 60% of the women 20-64 years old reported having a Pap smear within the year prior to the survey, and an additional 20% within the previous two years. The proportion of women reporting themselves as never having a Pap smear was greater among black, poor, older women and non-metropolitan residents,[17,18] which includes some of the women at highest risk.

A number of risk factors for cervical cancer have been identified.[19] Strong risk factors include start of sexual activity at an early age, multiple sex partners, socioeconomic status of partner, and use of barrier methods of contraception (protective). This last factor implies an important role for infectious agents such as herpes genitalis and, recently, the papilloma virus.[20,21]

Women who are not screened adequately and have any of the above characteristics constitute a major high risk group. There is evidence that many high-risk women often have missed the opportunity to be screened through their contacts with the medical care system. In a study of low income women,[22] 97 women with invasive cervical cancer admitted to selected hospitals were interviewed about their medical and Pap smear history. Their responses were confirmed through medical records documentation. Seventy-six percent of the women in the study were black, with half the women below poverty level and half 50 years and older. Fifty-two percent of the women with invasive cervical cancer had never had a Pap smear. However, 73% of these unscreened women had some contact with a physician on an ambulatory care basis during the previous five-year period, representing missed opportunities for screening.

A review of hospital records for over 400 women dying from cervical cancer revealed that 11.9% of these women had been hospitalized within five years prior to their initial diagnosis without receiving a Pap smear or cervical biopsy.[23] These again represent missed opportunities.

Screening women where they come in contact with the health care system, particularly at outpatient clinics, is a feasible way to reach many women. There are several examples showing the success of such practices. In a municipal hospital, every female outpatient seen at the obstetrics and gynecology department, and a group randomly selected from other clinics, were screened for cervical cancer.[24] This policy was then expanded to screen patients admitted to the hospital. The program increased case finding, shifted the distribution of cervical cancer toward in situ and decreased mortality in the high-risk population served by the hospital. The existing personnel at the hospital were adequate to screen these additional women as well as follow-up women with atypical smears. A similar experience was reported at a British general hospital where screening non-gynecological patients reached many women who would not otherwise have had the test.[25]

As a means of reaching low income women, it was reported[26] that all women attending the outpatient clinics at a municipal hospital were screened for cervical cancer. Most of the invasive cases diagnosed as a result of screening were from the gynecology clinic, probably because women who became aware that they had symptoms of cervical cancer presented themselves at the gynecology clinic. However, the highest percentage of CIS and dysplasia were from the dental and ear, nose and throat clinics, indicating the value of screening women attending clinics other than in the traditional female health care specialties.

Another facility which serves high-risk women and where the implementation of routine screening should be valued are the Sexually Transmitted Disease (STD) clinics. Screening programs implemented in STD clinics found abnormal cytology in 1-3% of the women screened.[27,28] Briggs et al[29] compared the prevalence of cervical dysplasia in women attending an STD clinic and a Planned Parenthood Clinic, where screening is done routinely. Dysplasia was found in 11.4% and 5.9% of the women screened at the STD and Planned Parenthood Clinics, respectively. The data from these studies suggest that screening high-risk women attending STD clinics can result in the detection of cervical cancer at early stages.

It has been found that the most effective way to achieve behavioral change and compliance is by providing information that is personally relevant through individual contacts.[30] Personal contacts are effective in initiating not only risk prevention behavior but also repeated utilization of health services. However, repeated Pap tests are carried out most successfully among women who can return to the same health service every time.[30] Using the above findings as guidelines, we can expect hospitals and clinics that serve women at high risk to be the best medium for regular screenings. Indeed, the Canadian Task Force on Cervical Screening has recommended that offering cytologic tests should be an integeral part of the services in clinics for venereal disease and family planning, WIC centers and clinics that serve prostitutes and women in prisons.[31]

Not all cases of invasive cervical cancer result from inadequate screening. While it has been assumed that the natural history of cervical cancer has a long pre-clinical phase, data that began to accumulate from repetitive screening programs made it apparent that some cases develop very rapidly, since they were found among women who had been recently screened.[32-34] More recent data from Alameda Country, California; Memphis and Shelby County, Tennessee; and Worcester, Massachusetts indicate that the percentage of such rapidly developing cases may be as high as 25% to 33%.[35-37] The average interval from the last negative cytological finding to a diagnosis of invasive cancer was a little over 2 years. No distinctive characteristics have been found so far to single out these women. In the case of the Massachusetts data, the patients with cervical cancer were chosen among an upper socioeconomic group of women, who are considered a low risk group.

This variation in the natural progression of the disease has raised the question of how frequently women should be screened. There has been general agreement that women who belong in the high risk category should be screened annually and all others every three to five years depending on their age. However, in view of the rapid development of the disease in some women, annual screenings have been recommended even for those not considered to be at high risk.[37]

III. Current Situation in Connecticut

Since the development of the Pap test in the 1940's and 50's, public health officials have suggested that invasive cervical cancer is a fundamentally preventable disease. In the 1960's and early 70's, many public health officials began to feel that the death of a woman resulting from invasive cervical cancer was a failure of the public health and cervical cancer screening systems. Several studies on invasive and in situ cervical cancer in the State of New York[39-41] showed that there was a relationship between the detection of in situ cervical cancer and the incidence of invasive cervical cancer and mortality, indicating that further improvement in screening for early cervical cancer could reduce the mortality from invasive cervical cancer still further.

Figure 1 shows the average annual age-adjusted detection rate of in situ cancer of the cervix for the State of Connecticut from 1935 to 1983. Following the advent of the Pap test in the late 1940's, there was a dramatic increase in the reported numbers of in situ cancer of the cervix. The data suggest that the Pap test was effective in detecting early stage cervical cancer. From 1945 until 1970, there was a progressive and steady rise in the rate of detection of in situ cervical cancer. However, this rise was interrupted shortly after 1970 and the rate has stayed level for more than a decade. These latter data suggest that the ability of current screening programs to detect early cancer has reached a temporary ceiling. Figure 2 shows the average annual age-adjusted incidence rate of invasive cancer of the cervix in the State of Connecticut for the same period of time. From 1935 to 1950, the rate of invasive cervical cancer declined slightly. However, after 1955, by which time there had been a marked increase in the use of the Pap test and the identification of in situ cancer of the cervix, there was a considerable decline in the rate of invasive cancer of the cervix until recently when evidence of a slight diminution in the reduc-

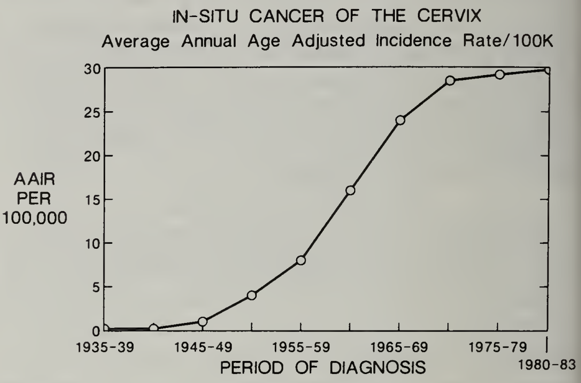

Figure 1

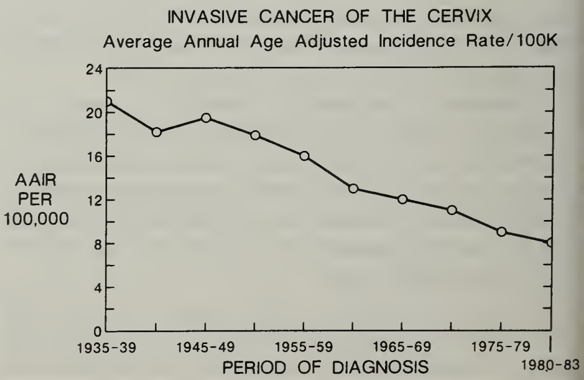

Figure 2

tion of the rate of cervical cancer began to appear. In the last few years, there has been some suggestion that rates of invasive cervical cancer, especially in very young women have plateaued or may be rising slightly.[42] Figures 3 and 4 show the same data for young women (<35 yrs.) only. In these women, the detection rates of in situ carcinoma continue to rise and the rate of invasive cancer shows signs of a slight and gradual rise since 1960. All of these data suggest that new efforts are needed to achieve the optimal reduction of invasive cervical cancer.

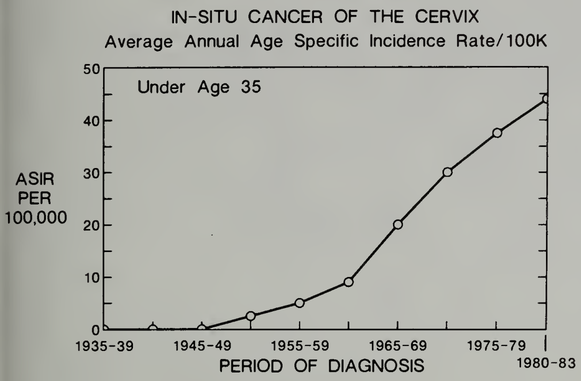

Figure 3

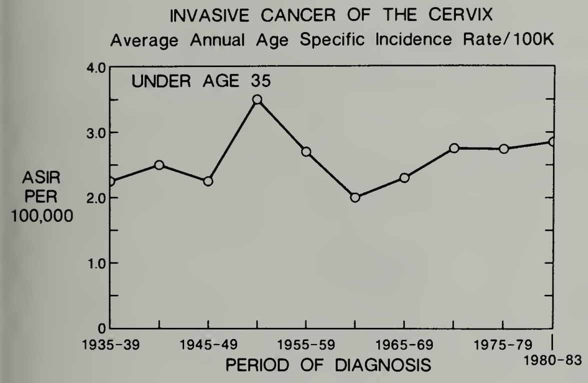

Figure 4

Table 1 shows the numbers and distribution of cervical cancer cases in the State of Connecticut during 1981. During that year, there were 151 cases of invasive cervical cancer and 567 cases of in situ cervical cancer diagnosed and reported in the State. The table divides these cases into the five Health Service Areas (HSA) of the State. These five HSAs are the operational regional sub-divisions of the Connecticut State Department of Health Services. Table 1 shows that the number of cases are divided fairly evenly through these five HSAs. If we take the ratio of in situ to invasive cervical cancer as one indicator of screening activity or of the success of screening activities, then the lower ratios in the south central and the northwestern HSAs indicate that we may need to make a major effort to enhance screening activities there. However, further study is needed to support that conclusion. In general, these data indicate that the State of Connecticut is ready for intensification of the cervical cancer early detection system.

The detection rate for in situ carcinoma of the cervix in Connecticut from 1935-83 for women over 35 years of age reached a peak at about 1970, and has dropped somewhat since. It is believed that all cases of invasive cervical cancer occur by passing through the in situ stage, and since there are still significant numbers of invasive cervical cancer occurring in Connecticut, the detection rate for in situ cancer is not yet high enough to include all women who eventually would be diagnosed with invasive cervical cancer. Therefore, we assume that a higher detection rate for in situ cervical carcinoma must be reached and maintained for some period in order to reduce or possibly eliminate the occurrence of new cases of invasive cervical carcinoma in the State of Connecticut.

It is possible that a program designed to eliminate invasive cervical cancer would need to raise the detection rate for in situ cervical cancer for women over 35 years of age, possibly up to the level seen about 1970, and to sustain the higher rate for several years in order to effect a significant additional reduction in the invasive cervical rate in the coming years. However, we recognize that the exact relationship between the in situ cervical cancer rate and the invasive cervical cancer rate, as it relates to the natural history and epidemiology of this disease, will need to be clarified further before a precise estimate of the reduced rate can be made.

It is not clear whether a higher detection rate of in situ disease can be reached for an extended period of time, but it is clear that the medical care system in this State was capable of screening and reporting 30.4 cases per 100,000 women in 1970. That level may possibly be achieved again for an extended year period. In turn, this higher detection rate for in situ disease should drive fur-

Table 1
DISTRIBUTION OF IN-SITU AND INVASIVE CERVICAL CANCER
IN CONNECTICUT BY HSA. 1981

HSA	*Total Population*	*Number of Cervical Cancer Cases*		*Ratio*
		In-situ	*Invasive*	*In-situ/Invasive*
S. West	635,220	127	30	4.2
S. Central	605,830	121	36	3.4
Eastern	510,770	86	21	4.1
N. Central	911,610	148	37	4.0
N. Western	506,240	82	27	3.0
Total State	3,169,670	567	151	3.8

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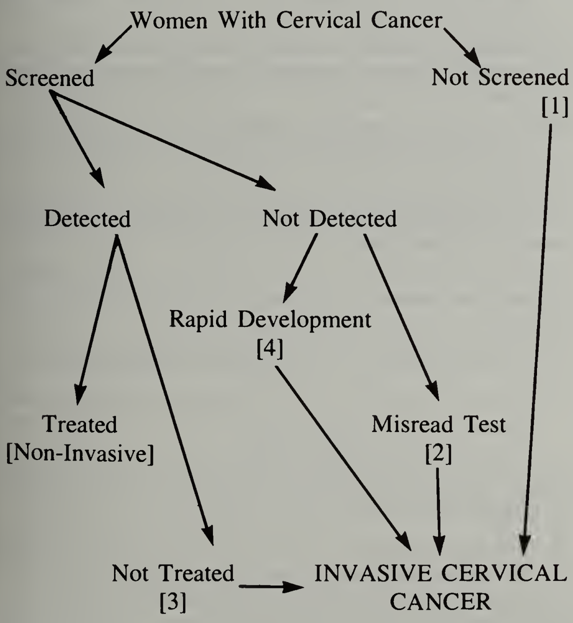
ther down the invasive cancer incidence rate, and eventually drive down the invasive cancer mortality rate in the State. For younger women, the in situ detection rate has not dropped, nor is the rate of invasive rate dropping.

IV. Proposed Approach for Connecticut

It is possible to visualize a plan to deal with invasive cervical cancer using the approach taken during the first half of this century when the maternal mortality review committees were established. The basic thrust of these committees was to refine the knowledge and existing skills of those physicians who managed pregnancy and childbirth through targeted education. These committees operated under the principle that maternal mortality was a fundamentally avoidable event. A committee could be constructed to operate under the principle that invasive cervical cancer is an avoidable event. Through such a committee, each case of invasive cervical cancer could be studied to identify the specific reasons that led to failure to detect invasive disease at an early and more treatable stage.

There are four ways that a woman can develop invasive cervical cancer in the context of screening and medical care as it exists today. A strategy for a system of interventions can be fashioned around the four routes to invasive cervical cancer, which are shown in the diagram below:



Routes 1-3 are to be dealt with by interventions that are designed to increase the efficacy of existing practices: adequate screening, accurate pap testing and prompt curative treatment of women with early stage disease. The fourth route, rapidly progressing disease that may be escaping existing cervical cancer screening strategies, is a special challenge. Through a series of special studies of the biological and clinical circumstances of rapidly progressing disease, the best available method for dealing with this form of the disease will need to be developed.

The four routes to invasive cervical cancer identify four categories that are broad enough to include the many variations in the reasons for failure that we may encounter. For example, Category [1] will include women "not screened," as well as women who had been screened at a time longer than three years prior to diagnosis. Category [3] will include not treated women, as well as those who appear to have had inadequate treatment or improper follow-up. Categorization of each case would take place through a committee called the Cervical Cancer Triage Committee.

The Cervical Cancer Triage Committee (CCTC) would consist of a gynecologic oncologist, a pathologist, and an epidemiologist, and other scientists and supporting staff as needed. The basic function of the Committee is fashioned after the maternal mortality committees of former years and will have the responsibility to review each new case of invasive cervical cancer to determine into which of the four categories they fall: [1] not screened; [2] inadequate Pap test; [3] not treated or improper follow-up and [4] rapidly progressing disease not detectable by ordinary screening methods. Although a few cases with incomplete information will be difficult to place into one of the four categories, most will be readily classified according to the diagram. This classification of cases will become the basis for the interventions described below.

One of the major reasons that women progress to invasive cervical cancer is failure to be screened with the Pap test during appropriate intervals. The Triage Committee can review each case of invasive cervical cancer and identify those women who were not previously reached by some aspect of the cervical cancer screening program in Connecticut. Their demographic and social characteristics will suggest the type and location of women who are currently not being reached for screening. Using this information, state agencies and organizations with existing mechanisms for outreach programs can be encouraged to implement a targeted screening intervention program. Use of the state's existing resources, such as clinics for family health, VD, etc., can minimize the cost of such a program.

An undetermined fraction of invasive cervical cancer cases progress to advanced disease because the Pap test slide was misread even though it was taken when the preinvasive stage was diagnosable. Through the Triage Committee's review, a portion of such cases can be identified for detailed study. It is possible that some factors associated with the probability of obtaining a false negative result can be identified.

A small fraction of the invasive cases may result from various reasons related to inadequate follow-up and treatment. These reasons can be identified by the Triage Committee and form the basis for recommendations to physicians, clinics and laboratories. In private practice this form of screening failures is infrequent; however, in some clinical outpatient situations, follow-up becomes difficult because patients cannot be located. Centralized follow-up, where needed or requested, can reduce the likelihood that this form of failure will occur.

Rapidly progressing cervical cancer offers a unique problem for early detection. It is possible that ordinary screening recommendations are not sufficiently frequent to detect some forms of rapidly progressing cervical cancer. Furthermore, women who have Pap tests according to usual time prescription for screening may feel quite assured that they have no immediate risk of cervical cancer and may ignore alarming symptoms of invasive disease for an unusually long period of time until the symptoms become compelling. It is necessary, then, that an accurate assessment be done of the nature and frequency of such rapidly progressing cases. That may be accomplished by analyzing all such cases identified by the Triage Committee in terms of their epidemiological as well as biological and clinical characteristics.

Through such analyses, it may be possible to identify a few characteristics that will indicate which group of women should be screened with a higher frequency in order to assure early detection of the disease. If such characteristics cannot be identified, it may at least be possible to develop recommendations regarding symptoms associated with the onset of rapidly progressing disease. This is not the most desirable outcome, since the disease is detected only after it becomes symptomatic, but it allows for treatment to begin earlier than it would otherwise. This type of intervention can be done through professional education of physicians and other medical personnel involved in the screening process.

It is hoped that the proposed strategy for the elimination of invasive cervical cancer in Connecticut can be tested in the near future, and that it will prove successful.

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The Connecticut Tumor Registry: Potential for Increasing Its Usefulness in Etiologic Research

MARY G. MCCREA CURNEN, M.D., DR. P.H.,
W. DOUGLAS THOMPSON, PH.D. AND JOHN T. FLANNERY, B.S.

ABSTRACT—Records from 1,572 cancer patients in the Connecticut Tumor Registry diagnosed in the years 1981-83, were reviewed to evaluate the usefulness of existing data on occupation/industry, smoking habits and family history of cancer. Useful information on occupation was recorded for 44% of patients and on industry/business for 37%. Data on smoking habits were given for 44% of patients and 59% of records contained information on family history of cancer. More women than men, 25 years of age and older, had usable information on occupation and industry; the reverse was true for smoking. Information on smoking was obtained in 72% of patients with respiratory cancers, in 59% of those with head and neck cancers but in less than 50% of patients with cancer at other sites. No systematic relationship was found between hospital size and percentage of usable information for the 4 items studied. Although 47.5% of cases were reported to the CTR within 3 months of diagnosis and 97.5% within 6 months, more rapid monitoring systems have been developed to facilitate early interviews of patients in case-control studies. With little additional time and money, tumor registries could include valuable information on key risk factors for cancer.

Introduction

The primary purpose of a population-based cancer registry is to accumulate complete and accurate information on malignancies. Registries also serve an important public health role in the conduct of case-control and retrospective cohort studies of cancer etiology. These studies, however, usually require more information than can be collected in the registration process alone. Nevertheless, the registry's database could be of greater use if it incorporated routinely collected standardized information on patient's occupation, industry/business and smoking habits and family history of cancer. These variables are useful in etiologic research as they reflect personal characteristics of cancer patients within groups of subjects of similar age, sex, race and primary site of cancer.

In this anniversary issue of *Connecticut Medicine,* other authors have reviewed the broad spectrum of studies to which the Connecticut Tumor Registry (CTR) has con-

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MARY G. MCCREA CURNEN, M.D., DR. P.H., Clinical Professor of Epidemiology and Pediatrics, Department of Epidemiology and Public Health, Yale University School of Medicine and Yale Comprehensive Cancer Center, New Haven, CT; Former Director of the Connecticut Cancer Epidemiology Unit, Department of Epidemiology and Public Health, Yale University School of Medicine and Medical and Scientific Director of the Connecticut Tumor Registry, Connecticut State Department of Health Services, Hartford, CT. W. DOUGLAS THOMPSON, PH.D., Assistant Professor of Epidemiology, Connecticut Cancer Epidemiology Unit, Department of Epidemiology and Public Health, Yale University School of Medicine and Yale Comprehensive Cancer Center. JOHN T. FLANNERY, B.S., Chief, Connecticut Tumor Registry, Connecticut State Department of Health Services.

tributed, both at home and abroad.[1] The registry still contains, however, a considerable amount of data which have not been adequately collected and therefore not fully utilized. In this study, we have undertaken to explore unpublished resources of the CTR with respect to occupation, industry/business, smoking habits and family history of cancer and to examine critically the quality of these data. The aim of this effort is to improve the quality, completeness and standardization of these data and to assure their inclusion routinely in the registry's database, making the information readily accessible to investigators.

Method

Data on occupation, industry/business, smoking habits and family history of cancer were obtained by reviewing in detail all original documents available in the patients' paper records at the CTR in Hartford. These documents are mailed periodically to the registry by each hospital's tumor registrar or record room staff. The CTR keeps a folder on each cancer patient which includes, for each primary cancer, a registration or "Tumor Record" form and copies of pathology, radiology and surgical reports, treatment protocols and follow-up data. Notes on admission and discharge diagnoses are frequently enclosed. However, the amount of documentation on cancer patients sent to the CTR varies markedly by hospital. The folder also contains, whenever available, a copy of the death certificate.

Our survey included 1,572 randomly selected CTR records for study. They were obtained from patients diagnosed during the 1981-83 period; among them 56% were females and 95% were white. During the past ten years, the CTR Tumor Record has, for each patient, requested information on "usual occupation" (or job held for the longest time) and "family history of cancer" without further specifications; the patient's industry/business or smoking status have not been requested on this form. For this survey, any information on the above variables was sought by careful examination of all documents in the patient's folder.

For the four variables of interest, we recorded the presence and quality of data on each patient as well as the patient's age, sex, race, primary site of cancer and hospital of diagnosis. This evaluation was helpful in identifying deficiencies in data collection by individual hospitals and in assisting physicians, tumor registrars and admitting staff to carry out responsibly their task of providing adequate data to the CTR.

The CTR has worked closely with hospitals over the years in order to improve the speed of reporting new cancer cases to the registry. Although the law stipulates that cases must be reported within 6 months of diagnosis or discharge of the patient, most hospitals have assisted the CTR by reporting cases sooner. We have also, in this study, investigated the time between diagnosis and hospital reporting to the CTR for each Connecticut hospital. This information is of particular interest to investigators who conduct case/control studies and wish to interview patients as soon as possible after their diagnosis of cancer.

Sources of Data

Data for our survey were obtained from all 35 Connecticut hospitals which admit cancer patients. These were grouped in five categories according to the yearly average number of first admissions for cancer. Table 1 presents the sources of data for the 1,572 records obtained from patients with newly diagnosed cancer during the 1981-83 period. The records were randomly selected and reviewed by one investigator. This survey included 4.4% of the 1981 and 1982 patients in the CTR registry, and 2.5% of those diagnosed in 1983. More records were selected from patients diagnosed in 1981 and 1982 than in 1983. This occurred because the main thrust of the study was to evaluate the quality of data prior to an increased effort by the State Department of Health Services early in 1983 to improve the collection of information on current occupation/industry and smoking status of cancer patients. As indicated in Table 1, the largest hospitals are designated as groups A, B and C and include a total of 13 hospitals, 11 of which have cancer programs approved by the American College of Surgeons (ACS). Groups D and E include a total of 22 smaller hospitals, 9 with cancer programs approved by the ACS.

Demographic Data

The Tumor Record provides information on the patient's date of birth, age at diagnosis, sex and race (white, black and other). Patients were stratified according to 3 age

Table 1

NUMBER OF RECORDS SURVEYED AT THE C.T.R. BY HOSPITALS. GROUPED ACCORDING TO AVERAGE NUMBER OF FIRST ADMISSIONS FOR CANCER EACH YEAR

Hospital				*Records*	
Group	*No./Group*	*Approved by A.C.S.†*	*Average No. of First Admissions for Cancer/Yr.*	*No. Surveyed*	*No./Hospital*
A	4	4	1,000–2,000	240	60
B	4	3	700–1,000	240	60
C	5	4	500– 700	300	60
D	8	5	300– 500	288	36
E	14	4	80– 300	504	36
Total	35	20	± 19,000	1,572	

†Cancer Program approved by the American College of Surgeons (A.C.S.).

groups: 0-24 years; 25-64 years and 65 years and over, and 2 ethnic groups: white and non-white.

Occupation/Industry (Business) Data

The Tumor Record provides space for recording the patient's "usual occupation" but not place of work. In Connecticut, a survey of hospital admission forms indicated that "occupation" of patient was mentioned on 68% of the forms and "industry/business" on 87%.[2] However, these forms were rarely sent to the CTR.

Smoking Data

No specific entry in the CTR Tumor Record for data on smoking was planned for in the past. If present in the patient's record, these data were most often found in the "History" section of the Tumor Record, together with data on drinking habits. Occasionally this information was found in an abstract of the patient's medical record when it accompanied the Tumor Record. In Connecticut, 29% of hospitals recorded the smoking status of patients on their admission form at the time of this study.[2] However, the hospital admission form was rarely found in the patient's record at the CTR as indicated above.

Family History of Cancer

Data on family history of cancer were not standardized but were entered under a specific heading in the Tumor Record, without further specifications.

Date of Diagnosis and Date of Reporting to the CTR

These dates were directly available on the Tumor Record. The date of diagnosis was entered on the Tumor Record by the hospital staff, while the staff at the CTR stamped the date of receipt directly on the front page of this document.

Data Analysis

A. Data on *occupation* were categorized in 3 groups:
   1. *Usable data,* i.e. which could be coded according to the US Bureau of the Census coding system;
   2. *Non-usable data,* i.e. retired, unemployed, helper, aide, employee etc.;
   3. *Missing data*

B. Data on *industry/business* were categorized in 3 groups:
   1. *Usable data,* i.e. which could be coded according to the US Bureau of the Census coding system; for specific occupations such as policeman, postal clerk, fireman, housewife etc., information on the business, even if missing in the record, was implicitly assumed and entered in this category;
   2. *Inferred data;* this group included business categories which could broadly be inferred because of data on occupation, i.e. barber, bartender, minister, nurse, etc., although the information on industry/business was missing in the record.
   3. *Missing data;* whenever business category could not be inferred from occupation.

C. Data on *smoking* were categorized in 2 groups:
   1. *Usable data* included any information on smoking habits;
   2. *Missing data*

D. Data on *family history of cancer* were categorized in 2 groups:
   1. *Usable data* included specific information on the patient's relationship to other family members with cancer at the same site or at a different or unknown site. For the purpose of this study, non-specific information on family history of cancer such as: unremarkable, non-contributory, negative, none, not applicable, was also considered usable data.
   2. *Missing data* included mention of "see previous admission" when data for that admission were not present in the record.

E. *Interval between diagnosis and reporting of cancer to the CTR*

   The time interval between the month and year of confirmed diagnosis of cancer in the hospital and the date of receipt by the CTR in Hartford of the patient's Tumor Record was computed in months.

Results

Table 2 indicates the proportion of records with *usable* information on occupation, industry, smoking habits and family history of cancer, by age and sex of patients. Subjects less than 25 years old represented only 2% of males and females in this study. As seen in this table, usable data on each of the four items of information were not available for the majority of patients. Usable data on occupation, were available for 44% of subjects; on industry/business, for 37%; on smoking, for 44% and on family history of cancer for 59% of subjects. More women than men had usable information on occupation and industry for patients 25 years and older but the reverse was true on smoking. Usable data on occupation and industry were found more frequently in records of patients who had not yet reached the usual retirement age of 65.

Non-usable data for occupation were recorded in 27% of patients while data were missing in 29% of records. Information on industry/business was missing in 59% of records. In addition, in 4% of records with missing data, the industry could be *inferred* from the patient's occupation.

Data on family history of cancer were more frequently recorded for females than for males except in young patients under 25 years of age.

When these data were examined by ethnic group (white/non-white), the percent of usable information for each of the 4 data items under study was similar for the two groups.

Table 3 indicates the percent of usable data for "occupation," "industry," "smoking habits" and "family history of cancer" by primary site of cancer. Occupation was recorded less frequently in patients with genito-urinary cancers

Table 2

PERCENT OF RECORDS AT THE C.T.R. THAT CONTAIN USABLE INFORMATION ON OCCUPATION, INDUSTRY, SMOKING HABITS AND FAMILY HISTORY OF CANCER, 1981-83, BY AGE AND SEX OF PATIENT

	Males					*Females*				
Age	*Occupation* %	*Industry* %	*Smoking* %	*Family History Of Cancer* %	*(N)*	*Occupation* %	*Industry* %	*Smoking* %	*Family History Of Cancer* %	*(N)*
<25	77	46	46	69	(13)	62	33	38	43	(21)
25-64	57	44	55	58	(260)	57	50	41	65	(391)
65 +	28	22	48	54	(416)	40	35	38	60	(471)
TOTAL	40	31	50	56	(689)	48	42	39	62	(883)

Table 3

PERCENT OF RECORDS AT THE C.T.R. THAT CONTAIN USABLE INFORMATION ON OCCUPATION, INDUSTRY, SMOKING HABITS AND FAMILY HISTORY OF CANCER, BY PRIMARY SITE OF CANCER AND SEX OF PATIENT

Primary Site	*Sex*	*(N)*	*Occupation* %	*Industry* %	*Smoking* %	*Family History of Cancer* %
Leukemia and	M	(47)	51	40	45	53
Lymphoma	F	(51)	55	43	45	57
	Total	(98)	53	42	45	55
Skin,	M	(33)	42	27	24	36
Bone and	F	(31)	48	48	39	55
Soft Tissue	Total	(64)	45	38	31	45
Respiratory	M	(149)	43	32	77	62
Tract	F	(78)	46	41	63	58
	Total	(227)	44	35	72	61
Head	M	(39)	44	31	67	54
& Neck	F	(27)	63	48	48	67
	Total	(66)	52	38	59	59
Central Nervous	M	(10)	70	40	60	40
System and Eye	F	(20)	45	25	35	60
	Total	(30)	53	30	43	53
Gastro-Intestinal	M	(197)	39	29	46	60
	F	(200)	43	37	39	59
	Total	(397)	41	33	42	59
Gynecological	F	(142)	51	45	35	65
Genito-Urinary	M	(198)	32	29	38	52
	F	(32)	50	38	34	56
	Total	(230)	35	30	38	53
Unknown Primary	M	(16)	44	25	38	56
Site	F	(32)	31	28	34	69
	Total	(48)	35	27	35	65
All Sites	M	(689)	40	31	50	56
	F	(883)	48	42	39	62
	Total	(1,572)	45	37	44	59

or in those with unknown primary sites than in other cancer patients. The reporting of industry by primary site of cancer did not vary substantially from the overall 37% for all sites combined. The best results were for leukemia and lymphoma patients in both sexes and for female patients with skin, bone, soft tissue, gynecological and head and neck cancers.

Smoking was recorded in 72% of patients with respiratory tract cancers, 77% in males and 63% in females. For other cancers, reporting of smoking habits was less than 50% except for patients with head and neck cancers (59%).

Information on family history of cancer was found in a higher percentage of patients with respiratory tract and gynecological cancers and with unknown primaries than in patients with cancer at other sites.

Table 4 presents data on the 4 items of information by sex and hospital of diagnosis. Hospitals are grouped according to their average number of first admissions for cancer per year, as indicated in Table 1. No systematic relationship was found between hospital size and the percentage of usable information. Individual hospitals did, however, vary considerably but not as a function of hospital size. No obvious characteristics of the hospitals distinguished those which did and did not provide usable information to the CTR for a large proportion of patients.

During the same calendar month as diagnosis, 3.2% of incidence cases of cancer in this study were reported to the CTR. During the first calendar month following the month of diagnosis, 16.2% had been reported. A larger proportion of cases were registered during the second (31.9%) and third month (47.5%) after the month of diagnosis than at any other time, representing in each case a 16% increased yield over the previous month. As indicated in Table 5, this percent increase in reporting gradually declined after the 3rd month to reach 77.5% by the 6th month and 97.5% by the 12th month after the month of diagnosis. Among the 2.5% of primary cancers not yet reported at that time, 35 were registered between the 13-18 months, 4 between the 19-24 months and one was reported more than 25 months after the month of diagnosis.

Table 5 also illustrates that hospitals in Group E (smaller hospitals) were prompt in reporting to the CTR: 58.1% of cases within 3 months and 83.5% within 6 months of diagnosis. At 12 months, however, 4.4% of cases had not, as yet, been registered.

Discussion

In 1980, a bill, introduced by the State Senator Michael J. Skelley, was passed by the Connecticut Legislature which stipulated that all newly diagnosed cancer patients had to have an occupational history included in their medical record.[3] Although implementation of this bill was not possible without funding, the CTR had a commitment to collect information on the occupation/industry of all patients in the registry. Our study was initiated to examine the extent and quality of information on occupation/industry which was received by the CTR thereafter. We surveyed a random sample of records from patients diagnosed in Connecticut hospitals during a period of 3 consecutive calendar years, 1981 through 1983. During the later part of this period, a plan was instituted for hospitals to collect routinely, on admission of *all* inpatients, regardless of diagnosis, data on *current* occupation, industry/business, and smoking habits, because we found that these data were frequently missing in the medical record. A Circular Letter from the Commissioner of Health[4] stipulated that on admission to the hospital, each patient must be asked to state for the record his or her current occupation and, if retired or unemployed, report the last job held. The name and address of the business or industry where the patient worked had also to be noted. In addition, data on smoking habits had to be recorded according to the patient's status as a person who is a current smoker, ex-smoker or one who has never smoked. A special form was sent to all hospitals to facilitate the collection of standardized data on these variables. Hospitals elected, however, to enter this information directly on their own admission form. The temporary form had been made available because the CTR was in the process of modifying its computerized data system. The new Tumor Record Form, which now includes these standard items of information, had not yet been issued. Although the Circular Letter was delivered

Table 4

PERCENT OF RECORDS AT THE C.T.R. THAT CONTAIN USABLE INFORMATION ON OCCUPATION, INDUSTRY, SMOKING HABITS AND FAMILY HISTORY OF CANCER, BY SEX AND HOSPITAL GROUP*

	Males					*Females*				
Hospital Group	*Occupation* %	*Industry* %	*Smoking* %	*Family History Of Cancer* %	*(N)*	*Occupation* %	*Industry* %	*Smoking* %	*Family History Of Cancer* %	*(N)*
A	48	21	55	63	(100)	48	31	44	70	(140)
B	33	31	49	41	(107)	50	42	33	41	(133)
C	50	27	58	70	(135)	54	36	42	77	(165)
D	40	31	55	61	(127)	47	48	44	68	(161)
E	33	37	42	49	(220)	45	46	36	56	(284)
TOTAL	40	31	50	56	(689)	48	42	39	62	(883)

*Hospital Grouped by Decreasing Number of First Admissions for Cancer/Yr.
See Table 1 for Definition.

Table 5

TIME INTERVAL BETWEEN DATE OF DIAGNOSIS AND DATE OF REPORTING TO THE C.T.R. FOR A RANDOM SAMPLE OF 1,572 RECORDS OF PRIMARY CANCERS DIAGNOSED BETWEEN 1981 AND 1983

Hospital Group	*Percent Reported Within 3 Months*	*Percent Reported Within 6 Months*	*Percent Reported Within 12 Months*
A	39.2	75	100
B	40.8	68.8	96.7
C	39.7	75.3	97.3
D	49.3	78.5	99.3
E	58.1	83.5	95.6
All Hospitals	47.5	77.5	97.5

in 1983, it was too soon for us to assess its impact on the collection of data from patients diagnosed in that year. It did elicit, however, prompt responses from hospitals which incorporated these items of information in developing their own computerized database for medical information.

Table 2 indicates that usable data on occupation were available in 44% of subjects, more in females than in males. In a study by Swanson et al[5] on the reporting of occupation (which included "unemployed" but excluded "retired") on abstracts of cancer cases in Metropolitan Detroit, information was available on 39% of females and 37% of males as compared to 48% and 40%, respectively, in the current study. Non-usable data, in our survey, were recorded in 27% of the records examined. This represents a considerable wastage of data. The yield of useful information on occupation could be considerably increased by standardizing the data. This is particularly true for such data entries as "retired" and "unemployed," which should mention the last job held.

Although the Tumor Record has an entry for "usual" or principal occupation, we believe that in the great majority of cases, the occupation listed in the patient's record was the "current" or last occupation. In patients for whom we also had a death certificate which records the "usual" occupation of the deceased, we found that this information was identical to that recorded in the CTR in 87% of the cases. When discrepancies occurred between "usual" and "current" occupation, it was mostly in females listed as housewives on the Tumor Record while the death certificate indicated a previous job.[6]

The "current" occupation or last one held, is easy to obtain from the patient on admission to the hospital since it does not require considering all past jobs in order to identify the one which was held for the longest time. The "current" job can be promptly checked for validity and is used by the U.S. Bureau of the Census for occupational statistics. Although we realize that, in some instances, past jobs may be different from current jobs and more relevant to the cause of chronic disease such as cancer, the "usual" job would be more time consuming to record, less reliable and more costly to obtain. There is, however, no definite consensus around the world on this matter. Among 81 population-based registries which contributed to "Cancer Incidence in Five Continents" in 1982, 18 collected data on "principal" (or usual) occupation; 22 on "last" (or current) occupation and 14 collected data on both. Only 33% of registries did not collect data on occupation.[7] As noted by Jensen,[8] these resources on occupational data have not been fully exploited.

A large proportion of records lacked data on industry/business (59% overall), although a previous survey indicated that this item of information was requested on 87% of hospital admission forms in Connecticut.[2] Hospitals have found it helpful to record the name and address of the employer in instances of third party payment. This information, however, is likely to be entered in the hospital's billing system and not necessarily made available to the hospital Tumor Registry. With the computerization of various hospital information services, the problem of record linkage will have to be addressed.

According to the 1980 Bureau of the Census coding system, the coding of occupation is dependent on industry.[9,10] Thus, both entries are essential for the satisfactory coding of data useful to assess occupational and industrial exposures. In a pilot study at Yale, a computerized dictionary has been developed for rapid and efficient coding of occupation and industry following the present coding system of the Bureau of Census. For this purpose, computer alphameric entries for occupation and industries (20 and 30 characters respectively) will have to be keyed into the CTR database.

Data on smoking were obtained from 44% of the records. Any information on smoking habits was considered acceptable for the sake of this survey. However, since the data were not standardized, their usefulness is limited. The differential in the reporting of smoking habits by primary site of cancer suggests that serious biases would result if attempts were made to monitor associations between cancer and smoking based only on data currently available in the CTR. As mentioned previously, on admission to Connecticut hospitals, the smoking status of patients will be noted by checking one of the following entries: smoker — ex-smoker — never smoked. The definition of a "smoker" needs also to be standardized. In a previous publication,[2] we reported on three different definitions currently in use. It is likely that in the future the percent of usable data on the smoking status of patients will increase since hospitals need this information for assigning patients to appropriate rooms.

Information on family history of cancer was obtained in 62% of female and 56% of male patients as noted in Table 2. However, all records with any information whatever on this item were included in these percentages. As no standard questionnaire was used, we do not know what specific information was requested from each patient. While data on family history of cancer in parents and grandparents can be used statistically to compute risks, this is not the case when cancer occurs in siblings, children, aunts and uncles, cousins etc., where denominators are unknown.

In case-control studies, the practicality of relying exclusively on the routine reporting mechanism of population-based registries for case identification is limited by the time lag between diagnosis of cancer in the hospital or private diagnostic laboratory and receipt of this information by the central registry. Table 5 indicates that the percent of newly diagnosed cancers in our study which were reported to the CTR within 3, 6, and 12 months after the month of diagnosis were 47.5%, 77.5% and 97.5% respectively. This compares favorably with the results of an earlier pilot study which included a random sample of 327 primary cancer patients diagnosed in Connecticut in 1981.[6] In this series the percent of cases reported at

3, 6 and 12 months after the month of diagnosis were 37.6%, 70.0%, and 96.0% respectively.

The promptness of reporting may have been influenced in the past by the hospital's case load and the availability of staff. However, there was no evidence in our study that hospital size played a major role, although small hospitals (Group E) had a greater number of cases reported within 3 and 6 months than larger hospitals. A rapid computerized ascertainment system has been initiated at Yale-New Haven Hospital and Comprehensive Cancer Center for the benefit of local users. This medical center provides 10% of all newly reported cancers to the CTR. Rapid ascertainment procedures have also been developed within the framework of the CTR registry itself. Study staffs, under the aegis of the registry and with the support of the Connecticut Hospital Association, have surveyed hospitals for newly diagnosed cancer patients by screening pathology and operative reports and abstracting medical record summaries with patients' discharge diagnoses. Nevertheless, these rapid monitoring systems need the back-up of the CTR. In the multicenter study of cancer of the breast, endometrium and ovary sponsored by the Centers for Disease Control (C.D.C.),[11-13] 15% of eligible cases in Connecticut would have been missed by the rapid ascertainment systems had it not been for their eventual identification through routine reporting to the CTR.

The primary task of a population-based cancer registry is to collect complete and accurate cancer data on all patients with the disease. With little additional time and money, however, the same database could include valuable information on key risk factors for cancer. In searching for causes of cancer, these data would be helpful in selecting subjects for case-control or cohort studies. Furthermore, they would serve to monitor the effects of exposure to environmental and personal hazards such as smoking.

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The President's Page

Let Us Not Self-Destruct

Sixty percent of physicians practice some type of office-based patient care service today. The majority of these patient care physicians are located in traditional solo, partnerships, or group practices. It is these physicians who are being subjected to competitive pressures that are being produced by the existence of Alternative Delivery Systems.

Alternative Health Care Delivery Systems have been proliferating in the State of Connecticut for the past five years. Entering on the Connecticut scene, however, is another movement involving the Voluntary Hospitals of America. The Teamsters Union in a joint venture with the Aetna Insurance Company and the Voluntary Hospitals of America are involved in establishing a PPO (Preferred Provider Organization) involving more than four hundred hospitals throughout the United States. Presently, on behalf of the Voluntary Hospital Association of America, officials in Hartford and New Haven are attempting to organize a network of non-for-profit hospitals located in key strategic marketing areas to control the majority of health care services necessary to sustain the existence of the participating hospitals. As a result, the remaining hospitals outside the "chosen network" are maneuvering to establish competing networks.

The next step is to enter into contractural arrangements individually or corporately with physicians to participate as a Preferred Provider Organization or as a Preferred Provider. More specific terminology should be "a contract provider organization or contract physician provider." The key word is contract.

There are many organizational, operational, and legal issues which are involved in the development of a PPO that are of concern to physicians. The primary drawback of the PPO concept for both physicians and patients is the loss of autonomy and control over the delivery of medical care to the patient. This can occur in several ways, namely, (1) through contract clauses which seek to restrict or define the scope of a physician's practice by directing specific referral patterns, and (2) by subjecting the physician's actions to utilization review and control processes which may not be designed and implemented by physicians.

The penetration of the Voluntary Hospital Association of America venture is causing great anxiety, confusion and paranoia on the part of the physicians of the State. At this point, physicians should be very concerned over the potential ramifications of these alliances on their own patient base. Physician's anxieties are turning into action. Joint ventures are being discussed at all levels. "Physicians Associations" are being organized. Isolated PPO's are being formed. The fear of further loss of rights and economic status is stirring further interest in the formation of a Physician Union.

The CSMS is actively involved in analyzing the multiple legal aspects of these networks. It is the obligation of the Connecticut State Medical Society to keep the membership informed on these matters. We must remember that the contracting process can be filled with uncertainty and potential pitfalls such as "hold harmless" agreements and contract clauses which may increase liability over which we have no control.

Heretofore we have had to deal with the Federal government and Third Party Payors. At present, we are having to confront on an increasing basis business corporations otherwise known as "The Fourth Party." In dealing with the Federal government, we have had recourse through legislative channels to effect change. Dealing with the "Fourth Party," it is a matter of confronting "bottom line" officials.

Recently, Woody Allen stated that "One path (before us) leads to disaster and the other to total extinction, I pray that we have the wisdom to choose wisely." I do not believe that our present problems are as irreversible as Woody Allen's. Some things cannot be changed but some things can still be changed. In the meantime, let us avoid self-destruction.

William A. Whalen, M.D.
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Reflections on Medicine

A Matter of Principle

ROBERT U. MASSEY, M.D.

"But our principles demanded it, and convinced of their virtue, I strove always to be consistent to them."

In her brief essay on *The Health of the Bride,* the painting reproduced on the cover of *JAMA* for June 7, 1985, Kathryn Simmons quoted the artist, Stanhope Forbes, who had written, in 1898, that his artistic creed was "to paint our pictures directly from Nature and not merely to rely upon sketches and studies which we could afterwards amplify in the comfort of a studio." He observed that this was not always easy to do, Nature being what she was.

Some of our first year medical students in their seminar on the quality of medical care have been wrestling with this matter of principles. In trying to make sense out of this year's fashion—HMOs, DRGs, PPOs, vertical and horizontal reorganization, and on and on—they quickly discover the flaw, the absence of principle, as they come to ask about what is behind this or that scheme, and how it will affect the behavior of physicians, hospital administrators, insurance companies, and patients.

"I'm going to do what I think is right no matter what the bureaucrats or administrators say!"

"Then what if you lose your privileges, or they tell you you can't work for their group or hospital anymore, or Medicare won't pay you?" asks another student.

"So be it. I want to be able to sleep nights."

There are signs of agreement all around, but they know that it will be years before they face the difficult professional choices. Today, the principles are still holding, the idealism that lighted and guided their way into medical school is just now facing the barest suggestion of a challenge.

Principles, like virtue, have fallen from fashion and from intellectual grace; too often when someone begins talking up the "principle of the thing," he is about to get himself into or out of some unprincipled act. But trying to make decisions without principles is like trying to do geometry without axioms.

A cartoon in one of the medical newspapers last spring showed a wrecker's ball being swung against the house of medicine; the implication was that the whole enterprise was about to come down; everyone was scrambling to have a say in whatever was to follow. The scrambling certainly is evident, but my hunch is that it is going nowhere. There is a standoff between the doctors on the one hand and all of the government, business, and investor interests on the other who stand to gain financially from the outcome. The doctors are looking for their principles; they remember that they had them when they came into medicine; they recall, with Osler, that "the profession of medicine is distinguished from all others by its singular beneficence."

In an earlier and simpler time we quoted the greats and were satisfied that we had made our point. No one needed to explain Francis Peabody. We appealed to universal principles, but now in an age of moral relativism, one principle is as good or bad as another, and consequently none is good for much of anything. When the vision of the Grail turns out to be an illusion, what's wrong with replacing it with a bottom line? One of my colleagues said recently that "it looks as though medicine is about to join the real world."

If so, we agreed that whatever esteem medicine had earned came from the "unreal" world we were about to leave, where some principles were better than others, and even the unprincipled knew the difference; where those who were troubled, in pain, sick, and helpless could expect to be cared for by men and women whose single-minded aim was "to cure sometimes, to relieve often, to comfort always."

The principle that making money should never come ahead of that obligation is so ancient as to need no defense, yet it is that principle that is under fire. No one pretends that all physicians have always been faithful, but most have acknowledged the principle, and their patients have counted on it.

"No one should approach the temple of science with the soul of a money changer," wrote Sir Thomas Browne in the 17th century. Paracelsus in the century before condemned the practitioner who worked "not out of love for the patient, which should be the physician's first virtue, but for the sake of money. Where money is the goal, envy and hatred, pride and conceit, are sure to appear. . ."

ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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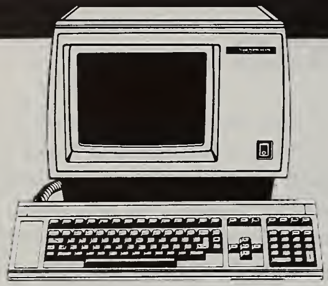

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Withholding and Withdrawing Artificial Feeding: The Role of the Living Will

JOSEPH M. HEALEY, J.D.

This month's column plays a dual role. It is the third of a three-part series dealing with Connecticut's recently enacted "death with dignity" statute.[1] It is simultaneously the first of a series dealing with the withholding and withdrawing of artificial feeding from patients at their own request or at the request of a legally-recognized surrogate. In my previous two columns, I described several of my concerns about the new statute. The statute focuses more attention on the process of gaining immunity from liability than it does on the process of protecting the declarant's right of self-determination. The provision requiring consent of next of kin permits the veto by a third party of the declarant's exercise of autonomy. The provision excluding pregnant women raises practical problems about the determination of pregnancy in all women of child-bearing age and constitutional questions about the state's power to restrict a woman's exercise of self-determination before viability occurs. In this column, some additional concerns related to the use of nutritional support will be identified and discussed as the first step in examining what has become a pressing issue for many health care providers.

Two provisions of the new Connecticut statute directly address the issue of nutritional support. Section 2 of the act provides that physicians or licensed medical facilities which remove or cause the removal of a life support system from an incompetent patient shall not be held civilly or criminally liable provided a series of conditions are met. Section 1 of the act defines "life support system" as:

> any mechanical or electronic device, excluding the provision of nutrition and hydration, utilized by any physician or licensed medical facility in order to replace, assist or supplement the function of any human vital organ or combination of organs and which prolongs the dying process;[2]

The effect of this provision is to exclude removal of nutritional support from the list of actions for which immunity may be sought in advance. Even more troublesome is the closing sentence of Section 2:

> If the attending physician does not deem the patient to be in a terminal condition, beneficial medical treatment and nutrition and hydration must be provided.[3]

Terminal condition is defined in the act as:

> the final stage of an incurable or irreversible medical condition which, in the opinion of the attending physician, will result in death.

This provision is especially troublesome because of its apparent requirement to provide nutrition in all circumstances, even when the contrary wishes of the patient have been clearly expressed beforehand. These provisions represent another set of barriers to respect for patient autonomy and dignity—a major goal of advanced directives such as the living will.

The exclusion of nutrition from the concept of "life support system" is an unfortunate but tolerable isolation of one means for the artificial prolongation of the dying process from others. As will be discussed in subsequent columns, there is a growing consensus that just as respirators and ventilators under certain circumstances represent "heroic" or "extraordinary" means to prolong life without benefit to the patient (and are, therefore, neither ethically nor legally required), so, too, under circumstances, artificial feeding may be "heroic" and "extraordinary" means which need not be employed. The separation of nutrition from life support system in the statute only means that immunity from liability will not be granted in advance to those who comply with the statute's provisions. More troubling is the second provision which on its face appears to require the use of nutrition in all cases which do not involve a "terminal" condition. The consequence of such a provision would be the violation of the common law of right of self-determination and the constitutional right of privacy of an incompetent patient who expressed instructions while competent about withholding various means of prolonging his or her dying process. This would be an unfortunate setback for the development of a reasonable policy dealing with decisions at the end of life. The only consolation is that this provision is unlikely to survive legal challenge.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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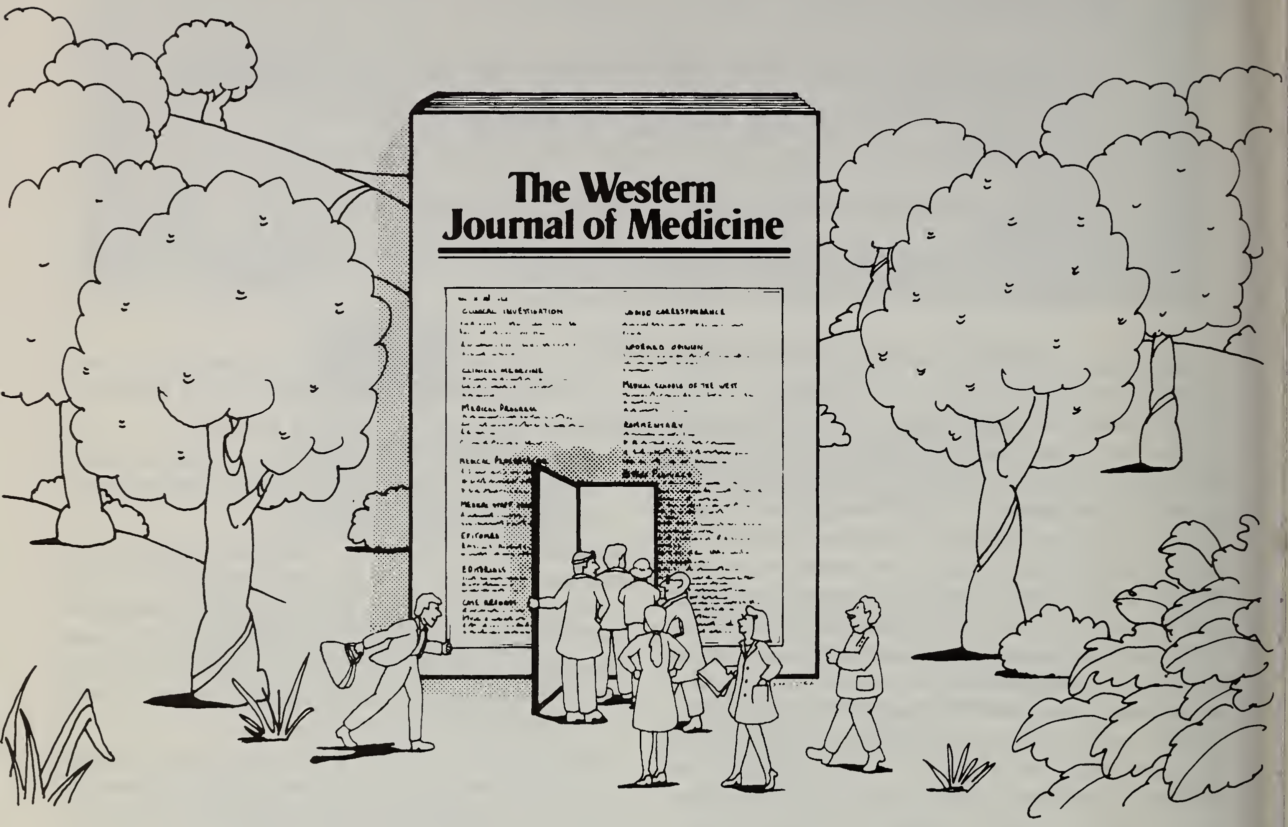
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Editorial

Connecticut Tumor Registry— The First 50 Years

This issue of *Connecticut Medicine* commemorates the Fiftieth Anniversary of the founding of the Connecticut Tumor Registry. Our Registry is the oldest population-based registry in the world, and as such, is a valuable resource for cancer researchers around the world.

In honor of the occasion, the International Association of Cancer Registries is holding its annual meeting in Hartford, Connecticut, on December 10-12th, and we extend a warm welcome to all of the participants.

Writing in a recent issue of *British Medical Bulletin*, Sir Richard Doll, wrote of the continuing importance of institutions devoted to documenting trends in disease incidence and distribution. He wrote, "With the development of such refined and powerful tools as the electron microscope, the mass spectrometer, and DNA probes, we turn naturally to laboratory investigation as our method of choice and the value of simple observational studies tend to be overlooked. This, I believe, is a mistake. The world has not become a uniform unit; culture, standards of living, and external environments vary greatly; and knowledge of the geographical distribution of disease is still far from complete."[1] Nowhere is this more evident than in the study of cancer, which remains a major health problem in much of the world. With foresight and fortitude, members of the Connecticut State Medical Society saw fit 50 years ago, to mount a statewide effort to upgrade the care of cancer victims in this area, and recognized at that time that careful documentation of cancer incidence and survival statistics, would be required if progress was to be measured over time.

That they have succeeded beyond all expectations is attested to by the fact that the Connecticut Tumor Registry and the information it has obtained over the years is cited repeatedly by a variety of investigators from around the world who recognize it as a source of reliable data dealing with cancer within the State.

Included in this issue of *Connecticut Medicine*, are several articles based on data collected by the Connecticut Tumor Registry and serve to illustrate how valuable these data can be in raising the public conscience regarding certain health hazards, as well as providing clues concerning potential etiological agents.

The Fiftieth Anniversary of the Connecticut Tumor Registry will also serve as an occasion to pay tribute to the many hard-working tumor registrars scattered throughout the state, and indeed the nation, whose dedicated service in cancer data abstraction and staging is vital to the function of any tumor registry.

Our congratulations go out to all the people associated with the Connecticut Tumor Registry over the past 50 years for a job well done, and our best wishes for continued success.

Jack W. Cole, M.D.,
Guest Editor

Ensign Professor of Surgery, Yale University School of Medicine; Formerly, Director, Yale Comprehensive Cancer Center.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

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REFERENCE

1. Doll R: Introduction. British Medical Bulletin, 40:4, p 307, October 1984.

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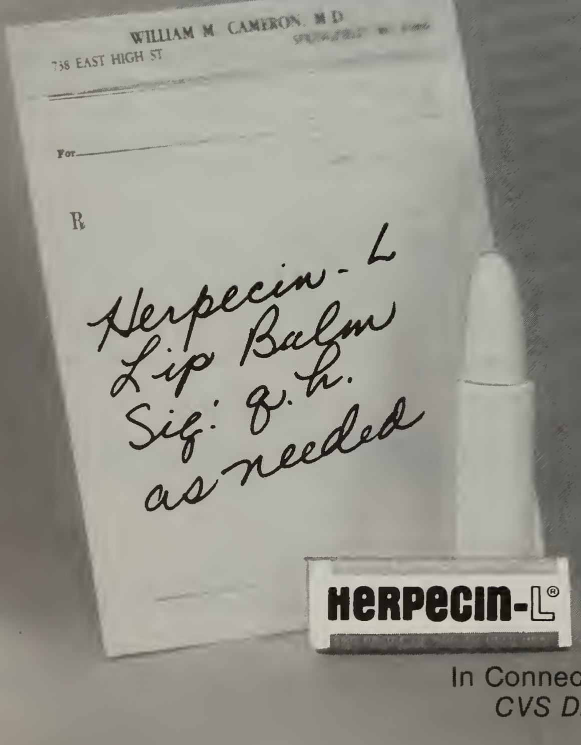

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Council Meeting

Wednesday, September 4, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Beck, Bobruff, Bonner, Czarsty, Freedman, Friedberg, James, Kaess, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Robbins, Rose, Sadowski, Schwartz, Sweet, Villa, Waldron, Welch, Whalen, Jr. and Zanker.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Dr. Fabro, Mr. Tomat (FCMA), Mr. Meister (NHCMA) and Mr. Coffey (HCMA).

Absent were: Drs. Ahrens, Canzonetti, Dardick, Reyelt, Jr., Scheer, Seide, Sullivan, Jr. and Zlotsky.

Reports from Physicians Serving on State and Federal Agencies

Dr. Guy W. Van Syckle reported briefly on the activities of HSA-V.

Dr. Jerome K. Freedman reported that CMIC had completed their computer hook-up with the Medical Inter-Insurance Exchange of New Jersey, which is the captive company of the Medical Society of New Jersey. He further reported that a full-time claims manager has been employed and the anticipated increase in premium was 17.6%.

Dr. Edward A. Kamens reported on CPRO activities including the criteria changes and loss of waiver status. He reported that CPRO had made 60,000 reviews and that pre-admission certification was required in one-third of the hospitals in the state.

Staff report on CSMS Monitoring of Planning and Regulatory Agencies was received as information.

It was VOTED that CSMS issue a press release to enlighten the public on the ramifications of the Medicare fee freeze and its effect on the elderly. Staff is to prepare the release and it is to be issued over the President's signature.

Report of the President

a. Dr. Whalen reported to the Council that he and Tim Norbeck appeared on a two hour radio program on WELI (on the subject of malpractice) on August 7 and also that CSMS is now sponsoring a Lifeline series that is appearing for 12 weeks on TV Connecticut Public Television Stations throughout the state. He reported that, from comments received, it appears that both of these programs are being well received.

b. He further reported on the upcoming Leadership Conference on September 4 and urged Councilors to attend this meeting and to inform their county officers of the importance of attending this meeting.

c. He recommended and it was VOTED that Joseph S. Sadowski, M.D. be appointed as alternate delegate to the Legislative Task Force. The delegate is R. Leonard Kemler, M.D.

d. Dr. Whalen further reported that he represented CSMS at a memorial service held for Leverett Hubbard, M.D., the first president of CSMS, at the Grove Street Cemetery in New Haven. He gave a brief background on Dr. Hubbard and placed a wreath on the tombstone.

e. Dr. Whalen briefly discussed the Status Report on Declaratory Ruling Regarding Prospective Payment Systems which was prepared by CSMS legal counsel. This document included the action taken to date on the challenge to the validity of certain regulations of the Commission on Hospitals and Health Care which require the submission of extensive patient and physician data by general hospitals. Legal counsel reported on the hearing held on August 19, 1985 before the Commission at which time testimony was presented by William Whalen, M.D. and Joseph Czarsty, M.D. Following extensive discussion, it was VOTED that anticipating an unfavorable ruling on the CSMS position, legal counsel should prepare a brief setting forth legal positions and objections to these regulations. It was further unanimously VOTED to reaffirm the action taken on June 15 as follows: "to support legal action in cooperation with other named plaintiffs to stay the data collection initiatives of the CHHC and to petition the Commission to declare its initiative illegal or continue the action in the courts."

f. Dr. Whalen discussed the action taken by CSMS thus far on the issue of the Podiatrists' claim that "the ankle is part of the foot . . ." and . . . therefore within the scope of podiatry practice in Connecticut. Legal counsel also discussed the report which they had prepared for the Council which included legal action taken to date. Following discussion, it was VOTED to authorize legal counsel, at their discretion and in consultation with the President of CSMS, to proceed to obtain a ruling from the Connecticut Medical Examing Board as to whether the practice of podiatry includes the ankle.

Report of the Executive Director

Tim Norbeck reported that a defensive medicine survey had been prepared and distributed to CSMS physicians. A heavy response may be very helpful to CSMS in its liaison work with the Legislative Task Force set up by the Connecticut General Assembly to study the medical malpractice insurance situation. Mr. Norbeck emphasized how important the Task Force activities will be to Connecticut physicians and that the Connecticut Trial Lawyers were mobilized to oppose any efforts to change the tort system.

Discussion of CSMS Annual Meeting

It was VOTED to appoint an ad hoc committee of not more than seven members to review the format of the annual and semi-annual meetings for the purpose of making recommendations to the Council two meetings before the 1986 annual meeting. Guy W. Van Syckle, M.D. is to serve as Chairman. Volunteers were requested to serve on this committee and the following names were forthcoming: Drs. Frank K. Abbot, William A. Whalen, Isadore H. Friedberg, Joseph C. Czarsty, Roger S. Beck, James C. Orphanos, Arturo D.P. Villa, Anthony D. Mancini, Richard D. Banyard and David H. Hild.

Nominations of Directors to the CPRO Board

A letter was received from the Chairman of the CPRO nominating committee requesting CSMS to submit at least four names to fill two terms which expire in October. It was VOTED to submit the names of Drs. Daniel W. Doctor, Mehdi S. Eslami, George A. Bonner and Isadore H. Friedberg.

Report of Medical Students on Attendance at AMA Meeting; Chicago, 6/13-17/85

Two reports, one from Eric Bernstein, President, Yale AMA Medical Student Section and one from Barry Weinstock, President, Yale Medical Student Council, were received as information. The Council was also informed that Eric Bernstein was given an award from the AMA/MSS Medical Student Outreach Program for outstanding achievement in MSS recruitment of 25 plus members.

Nominations for Positions on AMA Councils

It was VOTED that the CSMS AMA delegation look into the possibility of seeking support of the Council of New England State Medical Societies in running a Connecticut candidate for one of the AMA Councils.

Non-Member Attendance at Section Meetings and Society Functions

It was VOTED that non-members of CSMS should not be eligible to be representatives of CSMS at any formal Society meetings.

Physician Visits to Nursing Home Patients

Joseph Czarsty, M.D. and Richard Fiorentino, CSMS staff, reported on the recent meetings with Connecticut General representatives and other providers on the subject of physician visits to nursing home patients. Following discussion, it was VOTED "that the Council of CSMS support and be prepared to cooperate with medical specialty societies and other affected groups to assure that high quality of care is maintained for Medicare patients in nursing facilities, and that CSMS take a leadership role in this activity affecting physicians throughout the state."

Reply from AARP

A reply which was received from the national office of AARP to a letter from the CSMS Executive Director concerning prospective payment systems and DRG's was distributed to the Council with the agenda. It was VOTED that a copy of this communication be forwarded to James Sammons, M.D., Executive Vice President of the AMA for information.

Life Members

It was VOTED to receive as information the following names of Life Members:

Name	Town
Carl Bornemann,	Falls Village
William Kueffner	Southport
David Seligson	New Haven

Date of Next Council Meeting

Thursday, October 24, 1985

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on September 4, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

IN MEMORIAM

deSUTO-NAGY, ILONA, Royal Hungarian Medical School, 1915. Dr. deSuto-Nagy was an opthalmologist in the New Haven County area since 1943. She was assistant clinical professor at Yale University School of Medicine and a consultant at Waterbury Hospital. Dr. deSuto-Nagy was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 29, 1985 at the age of 92.

FEENEY, THOMAS M., Boston University, 1936. Dr. Feeney was a urologist in the Hartford County area since 1940. He was chief of urology at St. Francis Hospital and Medical Center and a consultant to Manchester Memorial Hospital, Rockville General Hospital, Winsted Memorial Hospital, the Institute of Living, and the state Veterans Home and Hospital in Rocky Hill. Dr. Feeney was president of the Hartford County Medical Association and the Connecticut State Medical Society and was a member of the American Medical Association; died August 3, 1985 at the age of 75.

JONES, ELWOOD K., College of Physicians and Surgeons, 1934. Dr. Jones was a general surgeon in the Fairfield County area since 1943. He was president of the attending staff at Bridgeport Hospital for nine years and was senior attending chief, section of general surgery. Dr. Jones was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 2, 1985 at the age of 77.

KLEIN, JOSEPH, Long Island College of Medicine, 1934. Dr. Klein was an obstetrician and gynecologist in the Hartford County area since 1946. He retired in 1978 as senior attending obstetrician and gynecologist at Hartford Hospital and a clinical associate of obstetrics and gynecology at the University of Connecticut Health Center. Dr. Klein was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died August 21, 1985 at the age of 74.

LINDENMUTH, WOODROW W., Jefferson Medical College, 1938. Dr. Lindenmuth was a surgeon in the New Haven County area since 1960. He was chief of surgery at the Veterans Administration Medical Center, West Haven, former chief of surgery at Yale-New Haven Hospital and had been a professor of surgery at the Yale University School of Medicine. Dr. Lindenmuth was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died August 2, 1985 at the age of 72.

LUBLIN, RAYMOND D., Johns Hopkins, 1929. Dr. Lublin was a general surgeon in the Hartford County area since 1932. In 1939, he founded the East Hartford Hospital. Dr. Lublin was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 23, 1985 at the age of 81.

PASQUARIELLO, D. WILLIAM, University of Naples, Italy, 1936. Dr. Pasquariello was a general practitioner in the Fairfield County area since 1937. He became the first chief of the family practice department at St. Vincent's Medical Center and was a founding member of the American Academy of Family Physicians in Connecticut. Dr. Pasquariello was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died August 4, 1985 at the age of 76.

SCHWARZ, H. PETER, University of Vienna, Austria, 1938. Dr. Schwarz was an internist in the New London County area since 1941. He was a senior attending in internal medicine at the William W. Backus Hospital, Norwich and a welfare department specialist in internal medicine and cardiology. Dr. Schwarz was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 12, 1985 at the age of 72.

TRACY, F. ERWIN, Yale University School of Medicine, 1929. Dr. Tracy was an internist in the Middlesex County area since 1929. He was senior attending, Medical Service, Middlesex Hospital, consultant at Connecticut Valley Hospital and Rocky Hill Veterans Hospital. Dr. Tracy was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March, 1985 at the age of 81.

Update: Evaluation of Human T-Lymphotropic Virus
Type III/Lymphadenopathy-Associated Virus Infection in Health-Care Personnel—United States

CENTERS FOR DISEASE CONTROL

The occurrence of the acquired immunodeficiency syndrome (AIDS) in intravenous (IV) drug users, blood transfusion recipients, and persons with hemophilia indicates that parenteral transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) occurs via infectious blood or blood products. Currently available practices have nearly eliminated these risks for transfusion recipients and persons with hemophilia. Because health-care personnel may be inadvertently exposed to the blood of AIDS patients, several studies have been conducted to determine the prevalence of HTLV-III/LAV antibodies in health-care personnel who have cared for these patients. Combining published results with data reported to CDC shows that, to date, 1,758 health-care workers participating in such studies have been tested for antibodies to HTLV-III. Twenty-six (1.5%) were seropositive, and all but three of these persons belonged to groups recognized to be at increased risk for AIDS. Epidemiologic information is not available for one of these three health-care workers who was tested anonymously. Because of the high level of interest in these studies and in the potential for occupational transmission of HTLV-III/LAV through parenteral and mucosal routes, the case histories for these two health-care workers are reported below.

Patient 1. A female health-care worker was tested for serum antibodies to HTLV-III in November 1984 as part of a study of hospital personnel. She had sustained accidental needlestick injuries in November 1983 and March 1984 (12 months and 8 months before) while drawing blood from patients with AIDS. At the time of enrollment in the study, serum antibodies to HTLV-III were detected by enzyme immunoassay (EIA) and Western blot techniques. No serum obtained before or within 12 months after the needlesticks was available for testing. She was in good health until June 1984, when she developed mild but persistent lymphadenopathy, most marked in the axilla. Beginning in August 1984, she experienced intermittent diarrhea. When interviewed by a physician, the patient denied IV drug use or blood transfusions and reported being heterosexually monogamous since 1981. Her long-term sex partner denied homosexual activity, IV drug use, or other known risk factors when interviewed separately. Although repeatedly antibody negative by EIA and Western blot methods over an 8-month period, HTLV-III was recovered from his peripheral lymphocytes in April 1985 but could not be recovered from lymphocytes obtained several months later.

Patient 2. A male laboratory worker was discovered to be lymhopenic after he volunteered to be tested in conjunction with a study in April 1985. At that time, he had serum antibodies to HTLV-III by EIA and Western blot methods. No previous blood samples were available for testing. As part of his job, he processed platelets pooled from individual donors for transfusion. In December 1983, he sustained an accidental cut on the hand while processing blood from a patient with leukemia. He also sustained an accidental needlestick injury in August 1984 while processing a unit of pooled platelets. Both incidents resulted in parenteral exposure to blood from other persons. It is not known whether any of the individual platelet donors or the patient with leukemia had HTLV-III infection. The health-care worker is asymptomatic, although he had transient cervical lymphadenopathy during early 1985. HTLV-III was recovered from his peripheral blood lymphocytes in September 1985. During three independent interviews, he denied any homosexual activity, IV drug use, foreign travel, or blood transfusions. He described himself as heterosexual and was not aware that any of his approximately 12 lifetime sex partners had AIDS or were at increased risk for HTLV-III/LAV infection.

(Reported by J Nadler, MD, S Landesman, MD, D Rechtman, MD, S Holman, MS, New York City, New York; J Groopman, MD, Boston, G Seage, MPH, Boston Dept of Health and Hospitals, G Grady, MD, Massachusetts Dept of Health; J Gerberding, MD, San Francisco, California; Environmental Epidemiology Br, Laboratory of Tumor Cell Biology, National Cancer Institute, National Institutes of Health; Hospital Infections Program, AIDS Br, Div of Viral Diseases, Center for Infectious Diseases, CDC.)

The two cases reported here represent the only known evidence of probable occupational transmission of HTLV-III/LAV in the United States. This confirms that the risk of transmission of HTLV-III/LAV infection to health-care workers from patients is extremely low. HTLV-III/LAV infections appear to be much less transmissible through needlesticks than hepatitis B; nearly 26% of persons comparably exposed to a hepatitis B surface antigen-positive patient develop infection. Nonetheless, personnel should follow recommendations designed to minimize the risk of exposure to parenteral or mucosal (e.g., blood spatter on conjunctiva) contact with potentially infectious materials from patients with AIDS or suspected AIDS.

Epidemiologic studies of needlestick injuries in hospital personnel indicate that over 40% of the accidents are potentially preventable if recommended precautions are followed when handling used needles or other sharp objects. Educational programs to familiarize health-care workers with the basic practices in infection control are essential to the prevention of AIDS and other infections. Health-care workers and others should become familiar with and follow recommended precautions when handling specimens, secretions, and excretions from persons known to be infected with HTLV-III/LAV. Health-care personnel whose serum is positive for HTLV-III/LAV antibody should follow the precautions that have been published for health-care workers with AIDS.

COMMITTEE SERVICE QUESTIONNAIRE
Connecticut State Medical Society

Early in 1986 the Councilors from the eight constituent county medical associations assume the responsibility of selecting members of the Society to participate in the various activities of the Society listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, all members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

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New Haven, CT 06511

Your cooperation will be appreciated.

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Medical Economics

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Professional Relations

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Public Affairs and Communications

☐ Editorial Committee of "Connecticut Medicine"
☐ Committee on Legislation
☐ Committee on Public Affairs

Scientific and Socio-Environmental Medicine

☐ Committee on Emergency Medical Services
☐ Cancer Coordinating Committee
☐ Committee on Drug Abuse Educational Programs
☐ Committee on Maternal Morbidity and Mortality
☐ Committee on Medical Aspects of Sports
☐ Committee on Mental Health
☐ Committee on Organ and Tissue Transfers
☐ Committee to Study Perinatal Morbidity and Mortality
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☐ Committee on Hospitals
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☐ Liaison Committee with Connecticut Pharmaceutical Association
☐ Liaison Committee with State Department of Income Maintenance
☐ Representatives to Connecticut Advisory School Health Council
☐ Delegates to Connecticut Public Health Association, Inc.
☐ Delegates to Connecticut Nutrition Council
☐ Delegates to Council of New England State Medical Societies

Please Return by January 10, 1986

Signed: ______________________________ M.D.
(Please Print)

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

FAMILY PRACTICE

Family practitioner. University-based HMO seeks inquiries and applications for staff positions. Competitive salary and benefits programs. Contact, Medical Director, Yale University Health Services, 17 Hillhouse Ave., New Haven, CT 06520. (Tel. 203-436-8433).

Mature Family physician, B/C, with many years of experience including industrial medicine, seeks full time work (no night call and no hospital call) with another family physician in a medical facility in Southern Connecticut. Please call (203) 372-0458.

Established, prepaid staff model HMO seeks an experienced board-eligible/certified family practitioner to staff our Wallingford Health Center. Unusual opportunity to meet the community's primary care needs where continuity of care, patient education/preventive medicine and high quality personal style are emphasized. CHCP has 42,000 members and is affiliated with Yale-New Haven Medical Center. Liberal benefit package. One opening available immediately, another starting July 1, 1986. Send C.V. and salary requirements to: Medical Director, Community Health Care Plan, Inc., 221 Whitney Avenue, New Haven, CT 06511. EOE M/F.

Family physician is seeking a full time family physician to work in a medical facility in a beautiful shoreline community. No night call. No hospital call. The practice is rapidly expanding. Experience in industrial medicine would be helpful. Send C.V. to CSMS, c/o FP/NN.

INSTITUTIONAL MEDICINE

Internist wanted as full-time staff physician for a 500-bed multi-licensed, JACH approved geriatric institution and for a continuing care retirement community in Central Connecticut. Geriatric experience preferred. Will work standard workweek, rotation of evening and weekend call. Send resume with salary requirements to: CSMS, c/o IM/BLS.

INTERNAL MEDICINE

Well-known group model Health Maintenance Organization seeking a well-trained, highly motivated general internist for a full-time position in the Stamford area. Contact R.S. Lyss, M.D., at (914) 682-7720.

Internist. B.C. with some cardiologic training for full-time position with large Southern Connecticut company. Outstanding career opportunity for ambitious individual in occupational and corporate medicine. Reply to CSMS, Box IM/SSS.

INTERNAL MEDICINE/FAMILY PRACTICE

CENTRAL CONNECTICUT area. Excellent opportunity for B/C or B/E internist or family practice physician in Burlington, just 20 minutes from Hartford. Near Boston, New York City. Possibility of solo or partnership arrangement. General income guarantee and benefits. Send CV to Megan Dineen, Bristol Hospital, Brewster Rd., Bristol, CT 06010 or call 9:00 to 5:00 (203) 589-2000, ext. 579.

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Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OB/WW.

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PRACTICE FOR SALE

Pediatric practice for sale due to retirement July 1986. Well established—Central Connecticut—Close to Hartford and New Haven. Terms negotiable. Write the CSMS Placement Service, c/o SALE/DD.

PRIMARY CARE

Southeastern CT area—Full and part-time positions available in Walk-In Medical Center in Groton/New London area. Seeking licensed physicians for day, evening, and weekend positions. Send reply to CSMS Physician Placement, c/o PC/LL.

Quality primary care physician needed to join internist and ER physician as a partner in developing a dynamic ambulatory care center in southern Connecticut. Those with serious interest should send CV and cover letter to CSMS, c/o PC/SS.

PSYCHIATRY

Cedarcrest Hospital, Newington, a 130 bed facility has a position for part time psychiatrist to work with a treatment team in the care of acute and intermediate care psychiatric patients. Night call also available if desired. Contact Arnold W. Johnson, Jr., M.D., Chief of Professional Services (203) 666-4613.

RADIOLOGY

Hospital based general diagnostic radiologist with special interest and training in invasive radiology is being recruited by six man radiology group for 100 plus general hospital in Northeastern Connecticut. Individual must have depth of experience necessary to initiate and manage interventional procedure program. Hospital currently offers full range of service including nuclear medicine, ultrasound, and mobile CT scan unit. New one-day surgical center just completed, also regional dialysis center and busy out-patient department. Send curriculum vitae to Jonathan Berger, M.D., 142 Echo Drive, Vernon, CT 06066.

Radiologist, planning retirement, seeks partner in busy, private practice. Write, CSMS, RAD/EE.

UROLOGY

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population; central location. Excellent opportunity for affiliation with a progressive medical and administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o UR/WW.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

FAMILY PRACTICE

July '86. Age 27. Nat'l bds. MD, University of Rochester, Rochester, NY; Int. and Res., York Hospital, York, PA. Prefers group or industrial type practice in a medium-sized community. Write, James L. Forsberg, M.D., 1433 Fourth Ave., York, PA 17403.

July '86. Age 28. Nat'l bds. MD, Albert Einstein College of Medicine, NY; Int. and Res., Stony Brook University, NY. Prefers solo or group type practice in a small to medium-sized community. Interested in all aspects of Family Medicine with the exception of Obstetrics. Write, Lanny Moskowitz, M.D., 665 #93 Belle Terre Rd., Port Jefferson, NY 11777.

Jan. '86. Presently in practice. Age 35. Nat'l bds. MD, University of Colorado; Int. and Res., Kaiser Hospital, Fontana, CA. Prefers group, associate or institutional type practice in a medium to large-sized community. Will consider OB. Write, Barry R. Hansen, M.D., 919 Emerson Pl., Claremont, CA 91711.

GENERAL PRACTICE

Sept. '85. Licensed in Connecticut. Age 33. Nat'l bds. AB cert. MD, UConn, Farmington; Int., Griffin Hospital, Derby; Res., Connecticut Valley Hospital, Middletown. Also interested in psychosomatic medicine and rehabilitation medicine. Prefers group, associate, institutional or industrial type practice. Write, Gary D. Gorman, M.D., P.O. Box 1604, Middletown, CT 06457.

Aug. '85. Age 43. FLEX. MD, University of Louvain, Belgium; Int., University of Louvain Hospitals; Res., West Suburban Hospital, Oak Park, IL. Has no preference to type of practice. Write, Thomas D. Coyne, M.D., 101 Moss Hill Rd., Jamica Plain, MA 02130.

GENERAL SURGERY

Jan. '86. Age 33. Presently in practice. AB elig. MD, King Edward Medical College, Lahore, Pakistan; Int., Lincoln Hospital Medical Center, Bronx, NY; Res., Lincoln-Misericordia affiliation, Bronx, NY. Prefers solo or group type practice in a medium to large-sized community. Write, M. Farrakh Ali Khan, M.D., 785 Oak Ridge Dr., Lisbon, ND 58054.

Immediately available. Presently in practice. Age 42. MD, University of Mosul, Iraq; Int., University of Rochester, NY; Res., Waterbury Hospital, Waterbury, CT. Prefers solo, group or associate type practice. Write, CSMS, c/o JK/SUR.

INTERNAL MEDICINE

July '86. Age 30. FLEX. AB elig. MD, University of Rome, Rome, Italy; Int. and Res., Framingham Union Hospital, Framingham, MA. Prefers group or associate type practice. Write, Thomas A. Hanna, M.D., 16 Trinity Drive, Milford, MA 01757.

Aug. '86. Age 36. Nat'l bds. AB elig. MD, George Washington University, Washington, DC. Int. and Res., University of Alabama Hospitals. Prefers solo, group, or associate type practice. Write, Les Gavora, M.D., 1206 Sharpsburg Circle, Birmingham, AL 35213.

July '86. Licensed in Connecticut. Age 28. Nat'l bds. AB elig. MD, University of Pennsylvania School of Medicine; Int. and Res., Hartford Hospital, Hartford, CT. Prefers group or associate type practice. Write, Eric L. Rosenberg, M.D., 100 Laura Lane, Apt. C-2, Rocky Hill, CT 06067.

Oct. '85. Age 29. FLEX. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital, Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional, or HMO type practice. Write, Nancy Irene Hoffmann-Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

Oct. '85. Age 36. Nat'l bds. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional or HMO type practice. Write, Dom P. Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

CARDIOLOGY. July '86. Nat'l bds. AB cert. MD, Hahneman University, Philadelphia, PA; Int., Res. and Fellowship, Long Beach Va Medical Center, Long Beach, CA. Experienced in angioplasty, pacemakers, nuclear medicine and doppler/echocardiography. Prefers group or associate type practice. Write, Brian C. Swirsky, M.D., 311 Ocean Ave., Apt. A, Seal Beach, CA 90740.

GASTROENTEROLOGY. July '86. Age 30. FLEX. AB cert. MD, Georgetown University School of Medicine, Washington, DC; Int. and Res., St. Elizabeth's Hospital, Tufts University, Brighton, MA; Fellowship, The Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC. Prefers group, associate or institutional type practice. Write, Thomas P. McMahon, M.D., Brookway West Condominium #E-8, Lewisville, NC.

PULMONARY. July '86. Age 30. Nat'l bds. AB cert. (IM), AB elig. (PUL). MD, University of Connecticut Health Center, Farmington, CT; Int. and Res., McGaw Medical Center, Northwestern Memorial Hospital, Chicago, IL; Fellowship, Cedars-Sinai Medical Center, Los Angeles, CA. Preference is for a pulmonary practice either hospital-based, a subspecialty group or a multi-specialty group. Write, Harlan R. Weinberg, M.D., 337 N. Palm Dr., #8, Beverly Hills, CA 90210.

PULMONARY. July '86. Licensed in Connecticut. Age 30. Nat'l bds. AB cert. MD, Johns Hopkins, Baltimore, MD; Int. and Res., University of Chicago, Chicago, IL; Fellowship, Yale-New Haven Hospital. Prefers group or associate type practice. Write, Ilene L. Rosenberg, M.D., 574 Skiff St., North Haven, CT 06473.

OBSTETRICS/GYNECOLOGY

Oct. '85. Age 34. Presently in practice. FLEX. AB elig. MD, Autonomous University of Guadalajara, Mexico; Fifth Pathway, University of Maryland; Res., Prince George's General Hospital and Medical Center, Cheverly, MD. Prefers group type practice or closed panel HMO in a medium-sized community. Write Gregory S. Rein, M.D., RR#1, Box 500, Woolwich, ME 04579.

PART TIME

Negotiable availability. Licensed in Connecticut. Presently in practice. Age 43. Nat'l bds. AB elig. MD, Int. and Res., India; Fellowship, William S. Hall of Psychiatry. Interested in all types of practice but only part-time. Write, Naimetulla A. Syed, M.D., Fairfield Hills Hospital, Newtown, CT 06470.

PEDIATRICS

July '85. Age 31. Presently in practice. Nat'l bds. AB cert. MD, New York University School of Medicine; Int. and Res., Rhode Island Hospital. Prefers solo, group, or associate type practice in a large to medium-sized community. Write, Andrew J. Schuman, M.D., RFD 2, Box 249B, Caribou, ME 04736.

PRIMARY CARE

Feb. '86. Age 32. AB elig. MD, University of Rome, Rome, Italy; Int., Long Island College Hospital, Brooklyn, NY; Res., Illinois Masonic Medical Center, Chicago, IL. Prefers group, associate or HMO type practice in a medium-sized community preferably in western Connecticut. Write, Eli R. Goldner, M.D., 2841 West Rosemont, Chicago, IL 60659.

RADIOLOGY

July '86. Age 29. Nat'l bds. AB elig. MD, SUNY at Downstate; Int., Staten Island Hospital; Res., SUNY Downstate; Fellowship, Cornell Medical College at North Shore University Hospital. Prefers solo, group, associate, institutional or industrial type practice. Write, Daniel J. Cohen, M.D., 167 First Ave., Apt. #7, New York, NY 10003.

UROLOGY

July '86. Age 33. Nat'l bds. AB elig. MD, Boston University School of Medicine. Boston, MA; Int. and Res., Vanderbilt University Hospital, Nashville, TN. Experienced in adult and pediatric urology. Prefers group or associate type practice in a medium to large-sized community. Write, Ned R. Novsam, M.D., 8300 Sawyer Brown Rd., E-306, Nashville, TN 37221.

Metastatic Pancreatic Islet Cell Carcinoma Causing Manifestations of Glucagon and Gastrin Hypersecretion

JOHN J. FERRARA, M.S., M.D., JOHN C. FUCCI, M.D. AND JAY B. BENSON, M.D.

ABSTRACT—A 59-year-old man received DTIC chemotherapy, resulting in remission of symptoms due to a glucagon secreting metastatic pancreatic tumor. Following cessation of therapy, he developed peptic ulcer diathesis and diarrhea which led to diagnosis of gastrinoma. The tumor, which had almost completely regressed following DTIC therapy, had enlarged and was again metastatic. Gastrectomy was required to control ulcer symptoms following a prolonged period of pharmacologic control with H-2 blockers. This combination of syndromes in a patients with a pancreatic tumor, though yet to be described, reaffirms the multipotential nature of islet cells.

The multipotential nature of pancreatic islet cell tumors has long been suspected. Documentation that a given tumor may contain or secrete a variety of hormones awaited improvements in both tissue histochemical staining and plasma radioimmunoassay techniques. Although biochemical evidence that a single islet cell tumor is able to manufacture two or more hormones is well established,[1-5] it is uncommon that a patient experience clinically apparent symptoms from multiple hormone secretion.[5-7] To our knowledge, the combination of Glucagonoma and Gastrinoma Syndromes in a patient with a pancreatic islet cell tumor has yet to be described. This report summarizes the case history of such a patient.

Case Report

A 59-year-old man was first admitted to the St. Francis Hospital and Medical Center in December 1979 for evaluation of skin rash and diabetes. Eight months previously he had developed a pruritic, erythematous, pustular, scaly skin rash on his right foot, which gradually migrated over his entire body excluding the face. Following trials with various topical preparations, he was treated with oral Prednisone (50mgm. daily), which resulted in clinical improvement. However, three weeks prior to admission the patient developed polydipsia, polyuria, fatigue, and epigastric pain accompanied by a four pound weight loss.

Past medical history was significant for a 30-year history of recurrent epigastric pain. His symptoms had been controlled, at first with antacid therapy, and more recently with short courses of cimetidine (300mgm qid). Oral cholecystography and barium upper gastrointestinal series, performed on several occasions, were normal.

Physical examination was normal except for the presence of a pustular erythematous rash on the right heel, buttocks, perineum, and anterior neck. Fasting blood sugar was 310 mgm/dl. Other laboratory tests including complete blood count, serum electrolytes, liver and renal profiles, calcium and amylase were normal. Control of the patient's diabetes was achieved through diet, 30 u.NPH insulin/day, and a tapering of Prednisone to 20 mgm qod. The patient was also placed on cimetidine (300 mgm qid) with relief of his epigastric discomfort by the time of hospital discharge.

The skin rash persisted, however, and he was referred to a dermatologist for skin biopsy. Microscopic examination demonstrated necrolytic migratory erythema (Figure 1), consistent with the Glucagonoma Syndrome. Serial plasma glucagon levels of 3,755 and 1,500 pg/ml (normal 175pg/ml) confirmed the diagnosis. The patient was admitted to the hospital in May 1980 for evaluation. At that time, he complained of severe diarrhea and weight loss. Physical examination revealed that the rash now involved his hands, knees and perineum; severe glossitis and stomatitis were present as well. Complete blood count, electrolytes, liver and renal profiles were normal; elevated serum glucose levels were brought under control by an increase in the NPH insulin dosage to 32 u daily. Serial fasting serum gastrin levels were 181 and 192 pg/ml (normal <150pg/ml).

Abdominal ultrasound (Figure 2a) revealed a 16 x 10cm. mass in the tail of the pancreas and another in the caudate lobe of the liver. Abdominal CT scan (Figure 3) demonstrated invasion of the root of the small bowel mesentery by the pancreatic mass and confirmed the presence of the hepatic lesion. Visceral angiography showed these tumors to be hypervascular, consistent with metastatic islet cell tumor.

The patient was started on a trial of DTIC at 250 mgm/m^2/day for five days at monthly intervals; therapy was well tolerated. The patient's rash gradually disappeared, which permitted a tapering of his prednisone to 10mgm. qod and NPH Insulin to 15 u. daily. An ultrasound study in February 1982 demonstrated apparent resolution of the hepatic mass. By January 1982 repeat ultrasound showed the pancreatic mass had decreased to 4.5cm. in diameter; a Glucagon level obtained at that time was normal. The mass was barely detectable in June 1982 (Figure 2b) and, as the patient was now free of all symptoms, chemotherapy was discontinued following the fifteenth course.

JOHN J. FERRARA, M.S., M.D., Assistant Professor of Surgery, University of South Alabama, Mobile, AL. JOHN C. FUCCI, M.D., Private Practice of Gastroenterology, Bristol, CT. JAY B. BENSON, M.D., Attending Gastroenterologist, St. Francis Hospital and Medical Center, Hartford, CT.

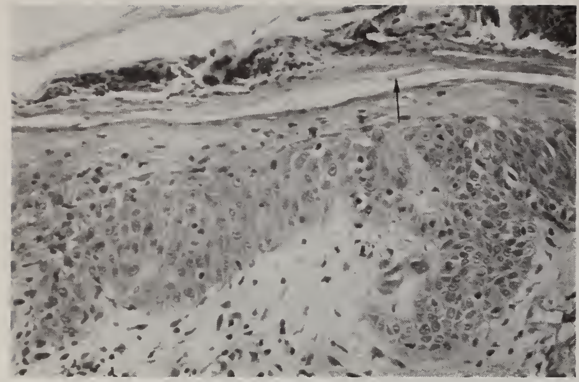

Figure 1
Necrolytic migratory erythema on skin biopsy. Note hyperkeratosis and epidermal necrosis (arrow). Perivascular lymphohistiocytic infiltration is present in the superficial dermis.

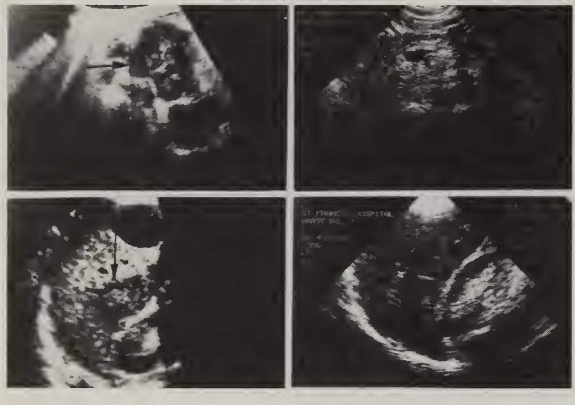

Figure 2
Representative sections taken from abdominal ultrasounds performed in May, 1980 (a) and June, 1982 (b). Note that the hepatic lesion (a, arrow below) has disappeared and the pancreatic mass (a, arrow above) has regressed a considerably—effects felt to be secondary to intravenous administration of DTIC.

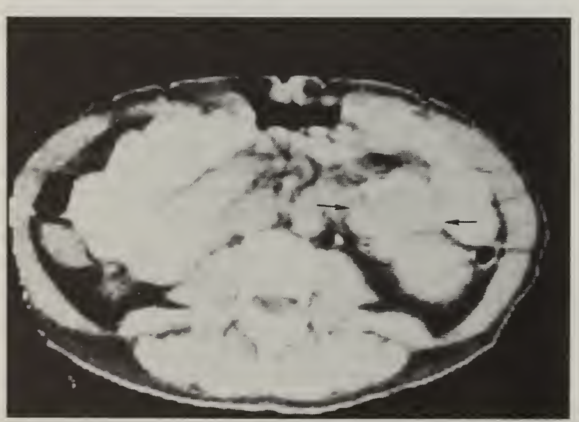

Figure 3
Computed tomagraphic scan (May, 1980) demonstrating a large pancreatic mass (arrows). A more cranial view identified the hepatic lesion in the caudate lobe.

The patient did well until December 1982 when he experienced postprandial epigastric pain. Abdominal ultrasound demonstrated enlargement of the pancreatic mass and reappearance of hepatic metastases. The serum glucagon was elevated to 530pg/ml; serum gastrin was 213pg/ml. Cycled DTIC therapy was reinitiated in an attempt to once again achieve regression of his metastatic tumor. During these treatments, the patient complained of severe epigastric pain which responded only to an increased dosage of cimetidine (600mgm qid). At that time, esophagogastroduodenoscopy was performed, demonstrating a large post-bulbar duodenal ulcer. Sucralfate 1gm. qid was added to the medical regimen, with further improvement in symptoms.

The patient completed five more courses of chemotherapy without incident. In August 1983, however, he developed severe diarrhea, nausea and abdominal pain. Family members also complained that the patient demonstrated wide mood swings and labile personality traits. Physical examination was normal. Serologic analysis revealed hypokalemia 2.5 milliequivalent/liter (mEq/L) which required aggressive replacement therapy. Serum glucagon was unchanged from its previous level (485pg/ml), but a fasting serum gastrin had risen to 286pg/ml. The diagnosis of Gastrinoma was confirmed by finding a greater than 100pg/ml increase in serum gastrin following the administration of secretin. An abdominal CT scan demonstrated the presence of a pancreatic mass in addition to an enlarging hepatic lesion. Upper endoscopy revealed severe erosive esophagogastroduodenitis, with partial healing of the post-bulbar duodenal ulcer.

All symptoms improved following several days of restricted oral intake and intravenous fluid resuscitation. Cimetidine was discontinued in favor of ranitidine (300mgm. po bid) and metoclopramide (10mgm. po qid). The patient was discharged only to return one month later with recurrent pain and profuse diarrhea. At that time his glucagon and gastrin levels were 450pg/ml and 708pg/ml respectively. Repeat endoscopy demonstrated multiple post-bulbar ulcerations in addition to diffuse inflammation of the esophagus and stomach. Treatment was changed from ranitidine to cimetidine (900mgm. qid) and Sucralfate (1gm. qid), again with clinical improvement. He remained well controlled until September 1983 when in addition to exacerbation of his epigastric pain he experienced progressive ataxia and mental dullness. Symptoms again abated following fluid resuscitation. An abdominal ultrasound revealed multiple liver metastases indicative of disease progression. It was therefore elected to place the patient on a chemotherapy regimen directed at metastatic Gastrinoma—Streptozotocin (500mgm/m^2 days 1-5) and 5-fluorouracil (400mgm/m^2 days 1-5 and 36-40). On day seven of the first trial, he developed fever, nausea, vomiting and intense burning in the throat. Oral thrush was confirmed by throat culture; distal esophageal candidiasis was confirmed by endoscopy, which also revealed multiple duodenal ulcerations. Laboratory analysis revealed pancytopenia; a near total absence of cellular elements on bone marrow aspiration confirmed the suspicion of a toxic chemotherapy reaction. He responded to intense hemodynamic support and antifungal therapy, and was discharged in good condition.

In December 1983, a second course of chemotherapy at one half the initial dosage was attempted but poorly tolerated and not completed. In addition, the patient's ulcer symptoms intensified, responding only after increasing the dose of cimetidine to 1200mgm. qid. Fulminant diarrhea resulted in readmission in February, 1984. The patient appeared weak and cachectic. The serum albumin was low (2.4gm/dl). Fasting serum gastrin had risen to 1,979pg/ml. An abdominal CT scan documented the progressive growth of both primary and metastatic lesions (Figure 4). Upper endoscopy demonstrated esophageal candidiasis and at least fifteen duodenal ulcers. He was kept without diet and placed on total parenteral nutrition, intravenous cimetidine (1200mgm. q6h) and oral antifungal agents. The patient's clinical status improved, and a repeat endoscopic examination demonstrated near total resolution of the candidiasis. However, there was worsening of the ulcerations despite aggressive medical therapy. An upper gastrointestinal series demonstrated thickened gastric folds, voluminous gastric secretions and marked duodenal ulcerations.

In March 1984 the patient was taken to surgery. Findings at celiotomy included an enlarged diffusely nodular pancreas and grossly abnormal para-aortic nodes. In addition, there were four large tumor deposits in the right hepatic lobe, the most prominent replacing the caudate lobe. Total gastrectomy with esophagojejunostomy were performed. An uneventful hospital course ensued, and the patient was discharged in good condition on post-operative day ten, requiring only 10 u. NPH insulin daily. As the patient was experiencing no symptoms from this metastatic hormone secreting tumor during short term follow-up, no additional therapy was recommended.

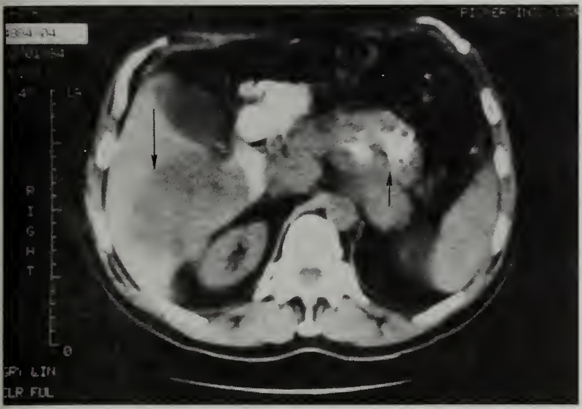

Figure 4
Computed tomagraphic scan (February, 1984) shows a large calcified pancreatic mass (short arrow), and large hepatic metastases (long arrow).

Discussion

There is ample documentation that, contrary to the earlier belief a pancreatic islet cell tumor produces at most one hormone, many contain or secrete a variety. This multipotential nature was initially confirmed by finding elevated levels of several peptide hormones in the serum of patients with known islet cell tumors.[8,9] The identification of different hormones within the cells of resected islet tumors, made possible by recent advances in histochemical staining techniques, has given further credence to this concept. In one histopathologic analysis of 24 islet cell tumors,[3] 29% were found to contain more than one peptide hormone. Others have examined these tumors under both light and electron microscopy[7,10,11] and have found two basic morphologic patterns: 1) a heterogeneous cell population, in which there are several cell types, each capable of secreting a single peptide hormone; 2) a homogeneous cell population, in which each cell contains many distinct types of secretory granules. That islet tumors exhibit this wide spectrum of development is probably related to the concept that, as members of the APUD family, the cells share common ultrastructural characteristics, embryologic origin, and genetic predisposition. Consequently, within each tumor there exists the potential for production of a multitude of peptide hormones, depending at least in part upon the stage of cellular differentiation.

Despite evidence that many islet cell tumors produce and/or secrete more than one hormone, they typically cause either no symptoms or a characteristic set of symptoms and signs secondary to the physiologic effects of a solitary hormone. It is far less common that a patient develop the clinical manifestations of more than one hormone syndrome. This variation between what is chemically determined and clinically identifiable in these patients is due to several factors, including: 1) the capacity for the tumor to secrete each of its products, 2) temporal fluctuations in the production/secretion of each hormone, 3) the ability of a hormone(s) to exert a dominant biologic effect(s) relative to the remaining hormones, 4) whether the summation of physiologic effects from each hormone results in clinically detectable disease.

In this regard, several reports[3,4] have described islet cell tumor production of glucagon and gastrin in patients with the clinical manifestations of gastrinoma alone. This report is unique in that it is the first known description of a patient who manifested the classic syndromes of both glucagonoma then gastrinoma, each serologically confirmed. His initial presenting feature was a migratory skin rash, characterized by pruritic, confluent, erythematous macules and vesicles. Dermal biopsy demonstrated findings typical of necrotizing migratory erythema; markedly elevated serum glucagon levels together with radiologic evidence of a hypervascular metastatic tumor of the pancreas secured the diagnosis of glucagonoma. The subject also exhibited some of the many other features typical of glucagonoma – glucose intolerance, weight loss, stomatitis, anemia, depression, hypoaminoacidemia, and a tendency toward deep venous thrombosis. As the tumor was beyond the confines of surgical control, it was elected to attempt control of his debilitating symptoms through the administration of Dimethyltriazenaimidazole (DTIC). Though there are conflicting reports as to the success of this therapy,[12,13] this subject exhibited a dramatic response documented by disappearance of the rash, improved control of glucose intolerance, decrease in serum glucagon levels, and ultrasonographic evidence of regression of both the pancreatic tumor and hepatic metastases.

The patient then experienced an increased severity of his longstanding peptic ulcer symptoms, together with diarrhea. Barium contrast studies and upper gastrointestinal endoscopy documented profound ulcer diathesis; markedly elevated serum gastrin levels, and a positive secretin challenge test confirmed the clinical diagnosis of gastrinoma. High dosage H2-blocker therapy initially controlled his ulcer symptoms in a fashion similar to that reported in the literature.[14] However, the patient did not tolerate combination Streptozotocin/5-fluorouracil chemotherapy, selected on the basis of its reported effectiveness in patients with this disease.[15] Ultimately, then, his ulcer symptoms proved refractory to medical management and total gastrectomy provided symptomatic relief.

In summary, this patient exhibited signs and symptoms diagnostic of, at first glucagonoma, then gastrinoma. It is interesting to note that during evaluation for the former syndrome, a history of peptic ulcer disease prompted screening tests for gastrinoma. Though barium contrast studies were normal, fasting serum gastrin levels were minimally elevated—indicative of the multipotential nature of his islet cell tumor. It is quite possible that, while DTIC chemotherapy prompted resolution of his dominant symptoms due to glucagon-secreting islet cells, it may have unmasked the clinical manifestations of gastrinoma. Thus, the clinician must be aware of the protean manifestations of pancreatic endocrine tumors and be alert for symptoms due either to multiple hormone secretion or a change in predominant hormonal secretion of a given tumor.

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Combined Disease of Schistosomiasis Mansoni with Sarcoidosis

SILVIO J. CASERTA, M.D.

Abstract—A Puerto Rican 32-year-old male became infected with Schistosomiasis mansoni and presented with extensive bilateral pneumonitis with pulmonary hypertension. Lung biopsy revealed the presence of non caseating granulomata with Schaumann's and asteroid bodies suggesting combined disease with sarcoidosis. There was no significant therapeutic response to steroids. Schistosomiasis is a common infestation in patients originating from Puerto Rico and Latin America.

With the great influx of citizens from Puerto Rico and Latin America, Schistosomiasis has become a disease of more than academic interest. Among the Puerto Rican population alone, the incidence has been reported[1] to be almost one-third who are infected with the Schistosoma confirmed by post-mortem studies. The variety seen in these areas is Manson's Schistosomiasis.

Case Report

This was a repeat admission of a 32-year-old Puerto Rican male who presented with an unresolved pneumonitis in both lower lobes on July 20, 1972. On his initial admission June 6, 1972 he had experienced fever and ill defined muscular aches, particularly over the anterior portion of the chest bilaterally of three to four days duration. It was associated with dyspnea on mild exertion and wheezes. With am-

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SILVIO J. CASERTA, M.D., Former Consultant, Department of Internal Medicine, Division of Pulmonary Disease, St. Vincent's Medical Center, Bridgeport, CT.

picillin, the temperature became normal, but in the interim the patient continued to be dyspneic on slight exertion, and he became aware of increasing generalized weakness. He had lost eight pounds, and he now stated that he had suffered from "asthma" for a number of years.

The past history revealed treatment for "pneumonia" at another hospital four months prior to this admission. He had worked in a foundry, melting cadmium for two years. Urine samples taken every three months for cadmium were considered to be at minimum levels. He smoked two packages of cigarettes a week.

On examination the patient showed signs of weight loss. He was not in any apparent respiratory distress. The temperature was normal, the pulse 88, and the blood pressure was 126/72 mm Hg. There was no peripheral adenopathy palpable. The lungs were clear and the heart sounds were normal. The rest of the examination failed to reveal any other abnormality.

Xrays of the chest on July 20th compared with the films of June 17th showed essentially the same bilateral basal infiltrates. There was compression by the infiltrate with greater involvement of the left mid lung field suggesting now involvement of the superior segment of the left lower lobe. An electrocardiogram showed negative T waves from V_1 to V_4; consistent with non specific changes.

The hemoglobin was 16.9 gms, white-cell count 6,500 with 72% neutrophils, 6% eosinophils and 22% lymphocytes. Platelet count was 165,000. The serum calcium, urea nitrogen, rheumatoid and antinuclear factor, sputa for acid fast, culture and cytology were all normal. The serum albumin was 3.8 gm per 100 ml and the serum globulin 3.4 gm per 100 ml. On electrophoresis, the gamma fraction was elevated to 24.2% the normal range being 13 to 17%. Sedimentation was 13mm and the VDRL, non-reactive. On room air the arterial gases were $p0_2$ of 77mm Hg, $pC0_2$ 46mm Hg, and pH 7.43. Pulmonary function tests revealed a peak flow of 235 liters per minute, FEV_1 1.30 liters, FEV_3 1.40 liters, vital capacity 1.40 liters, FEV_1 % of vital capacity 95%; and FEV_3 % of vital capacity, 100%. The conclusion was: Presence of moderate to severe restriction with no airway obstruction. Several urinalyses, Lee White clotting and prothrombin time were all normal. Skin testing for PPD intermediate, histoplasmosis and coccidioidomycosis were all negative but "second strength" (100 TU) was definitely positive.

The temperature curve remained flat but the patient continued to have dyspnea on the slightest exertion as well as rather severe generalized weakness. On July 29th a repeat white-cell count was 9,300 with 18% eosinophils, 2% stabs, 61% neutrophils, and 19% lymphocytes. The initial specimen of stool was negative for parasites, but then four specimens became positive for ova of Schistosoma mansoni.

Repeat X-rays of the chest on July 21st showed a diffuse infiltrate involving both lung fields with greater involvement at the lung bases, suggesting either congestive heart failure with pulmonary edema or a diffuse pneumonia. Laminographic examination on July 25th showed multiple patchy areas of infiltrate throughout both lung fields. The hilar shadows were enlarged with slightly nodular configuration suggesting lymph node enlargement. The combined findings suggested the p.i.e. syndrome (pulmonary infiltrate with eosinophilia).

A liver scan reported slight impairment of the radioactivity within the liver which could be within normal limits. A liver biopsy done August 2nd showed extensive acid hematin deposits in Kupfer cells. There were scattered periportal granulomas, rich in eosinophils. A few contained typical Schistosoma ova. A barium swallow for evidence of esophageal varices was normal.

The patient was started on betamethasone (celestone) .6 mgm four times a day on August 5th and decreased to twice a day on August 13th for two weeks. On August 11th he was given 2.5cc of stibophen (fuadin) intramuscularly the first day, 3.5cc the second day, 5cc the third day and then 5cc I.M. every two days for six doses. The patient after the conclusion of therapy showed no significant improvement. On August 22nd an open lung biopsy with frozen section was done of the right lower lobe. The lung tissue described by the surgeon was found to be very heavy, and there were numerous small areas of granulations no larger than miliary seeds which appeared to be confluent. A small portion was submitted for acid fast smear, routine and fungal cultures; which proved to be negative. The pathologist reported receiving a wedge-shaped, reddish tan, meaty lung tissue measuring 2 cm in the greatest dimension. A section showed tiny, grayish-soft, velvety nodules in the parenchyma. A Shistosome ovum was identified in the frozen section. Microscopically, the section showed miliary epithelioid granulomata scattered throughout the lung parenchyma containing calcified Schaumann's bodies in the center. Infrequent asteroïd bodies were noted in foreign body giant cells.

Diagnosis: Miliary noncaseating epithelioid granulomata of the lung with Schistosomiasis mansoni.

Comment by the pathologist: We would not exclude the possibility of concomitant Bresnier Schaumann's disease.

On August 25th the temperature postoperatively rose to 103 degrees rectally. The temperature decreased to 102 degrees on August 24th, 101.6 on August 25, and then became normal throughout the rest of his hospital stay. The post-operative course was rather stormy, the patient at times becoming noticeably cyanotic. Thereafter he stabilized quite well. He was ambulatory at the time of discharge.

Two months later, during an admission under the care of Christopher Boreyko, M.D. at Bridgeport Hospital, a right cardiac catheterization revealed the right atrial pressure to be 7mm Hg, right ventricular pressure 52/7mm Hg, pulmonary artery pressure 50/25mm Hg and wedge pressure 10mm Hg. After 15 minutes of oxygen inhalation, the mean pulmonary artery pressure decreased by only 4mm Hg indicating the presence of only minimal vasoconstriction. The patient received betamethasone (celestone) .6 mgm four times a day for nine days and twice a day for another 18 days. Clinically, he showed no significant improvement.

Subsequently the patient left to reside in Puerto Rico. A communication with his sister indicated that his current clinical status has further deteriorated with increasing pulmonary insufficiency. He now uses oxygen frequently at home.

Discussion

Most of the Schistosome eggs[2] are trapped in the intestinal wall or are impacted in the small venules of the liver. The subsequent granulomatous and fibrotic responses lead to the development of periportal fibrosis, hepatosplenomegaly, portal hypertension and portosystemic collaterals. Shistosome eggs[3] may bypass the liver and become trapped in the pulmonary vessels; granuloma formation and scarring may result in pulmonary hypertension and cor pulmonale. Liver function remains relatively normal because the parenchymal cells are not directly involved and sinusoidal perfusion is unimpaired. The major complication of this syndrome is hematemesis from esophageal varices.[4]

The more detailed workup on the second hospital admission to include particularly the lung biopsy suggested the presence of two diseases, namely, Schistosomiasis mansoni and probably sarcoidosis. The patient undoubtedly was infected with the former disease. There were four positive stool specimens for Schistosome ova, marked eosinophilia, positive liver biopsy, suggestive evidence radiologically of the p.i.e. syndrome, the increase in gamma globulin and the positive geographic area. The question then was: what could be the primary disease causing the pulmonary infiltration and pulmonary hypertension?

Cardiopulmonary Schistosomiasis is seen almost exclusively in patients with hepatosplenic disease and affects about 15 percent of these.[5] The development of portal hypertension leads to collateral circulation from the portal to pulmonary circulation. Findings of needle biopsy of the liver[6] is almost never adequate to make the diagnosis. The presence of Schistosome eggs in the biopsy specimen is no more revealing than positive findings on stool examination of rectal biopsy. Of critical importance is an adequate specimen revealing the characteristic pattern of periportal fibrosis sparing the parenchyma.[6] Cerri et al[7] reported ultra sound findings in 103 patients with hepatosplenic Schistosomiasis mansoni. The abnormal findings correlated well with the pathologic and anatomic characteristics. They concluded that ultra sound is quite helpful in making the diagnosis. Their main criteria include portal fibrosis with involvement of the gall bladder, hypertrophy of the left hepatic lobe and widening of the portal veins.

The lung biopsy yielded no conclusive findings for a definitive diagnosis. They were not characteristic of pulmonary Schistosomiasis with pulmonary hypertension. Sadigursky and Andrade[8] in 32 autopsy cases in Schistosomal cor pulmonale found two distinctive types of focal changes, namely: (a) within the alveolar tissue the eggs appeared in the center of discrete granulomas composed of epithelioid and giant cells and (b) presence of well preserved eggs within the lumina of pulmonary arteries and arterioles accompanied by fibrin deposition and marked endothelial proliferation. In 78 cases at necropsy of Schistosomiasis with advanced portal hypertension causing portopulmonary collateral circulation. Andrade ZA and Andrade SG[4] concluded that only with massive egg embolization to the lungs, the changes of arteriolitis, arteritis as well as parenchymal granulomata are seen with the arrival of the Schistosome eggs in the arteriolar collaterals. These were not the findings demonstrated in the lung biopsy of the case presented.

Clinically, the diagnosis of sarcoidosis did not suggest itself. Supporting evidence for making it the primary diagnosis was: (a) the presence of diffuse miliary noncaseating granulomata with detection of Schaumann's and asteroid bodies in the lung biopsy (b) apparent exclusion of all diseases provoking these lesions. Fungal diseases can be ruled out. The normal sedimentation rate, absence of any significant fever and lack of progressive disease would make tuberculosis a remote possibility. The rather minor environmental exposure in the foundry did not appear to be a significant factor.

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Pediatric Nasolacrimal Obstruction: Update on Management

RICHARD L. PETRELLI, M.D.

Abstract—Successful treatment of pediatric nasolacrimal obstruction requires early recognition of the problem and a systematic approach. An understanding of the embryology and anatomy of the nasolacrimal system is required. Surgical probing of the system should be undertaken when conservative treatment with antibiotics and massage are ineffective. Turbinate fractures and silicone intubation are beneficial in complicated cases.

All too often, young children with congenital nasolacrimal obstruction are not seen soon enough for management of their problem. Successful treatment depends in large measure on early recognition and surgical probing of patients who fail to respond to conservative medical management.

Any discussion of congenital nasolacrimal obstruction requires a review of the anatomy and embryology of the nasolacrimal system. Normally tears enter the superior and inferior canaliculi through the lacrimal puncta, then flow on to the lacrimal sac, the lacrimal duct, and into the nose (Figure 1). The lacrimal duct carries tears and runs through the medial wall of the maxillary sinus to

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RICHARD L. PETRELLI, M.D., Assistant Clinical Professor of Ophthalmology and Director, Oculoplastic Clinic, Department of Ophthalmology, Yale University School of Medicine; Attending Surgeon, The Hospital of St. Raphael, New Haven, CT.

empty beneath the inferior turbinate at the inferior meatus.

Embryologically, the rudiments of the lacrimal system are present in the 15 mm embryo as an epithelial cord. At about six weeks, the epithelial invagination begins at the naso-optic groove and this rod of cells moves toward the lacrimal fossa. Soon the central portion thickens to form the lacrimal sac, while epithelial buds push superiorly to form the canaliculi. At about three months, canalization begins, first in the tear sac, then the canaliculi, and last in the nasolacrimal duct, which is completed at about the time of birth.[1]

Malformations can occur at any point during development and may result in congenital fistulas from the nasojugal fold to the tear sac, absent puncta, canaliculi, or duct.[2] The most common form of obstruction is failure of complete canalization of the nasolacrimal duct at its most distal portion near the inferior turbinate. In fact, in as many as 30% of neonates, the distal portion is closed at birth.[3] Spontaneous resolution of the imperforate meatus occurs in most cases in the early post partum period. Two to four percent of neonates remain symptomatic and require further treatment.

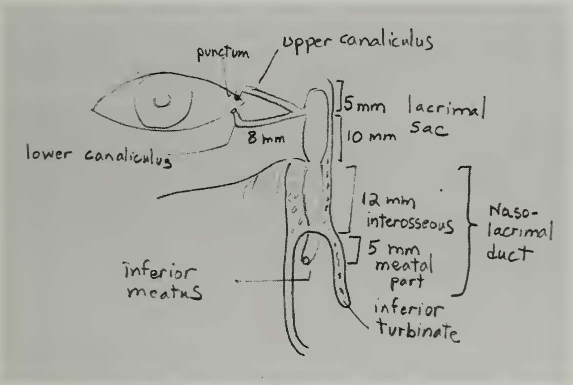

Figure 1
The upper and lower canaliculi join the lacrimal sac which empties into the nasolacrimal duct. The duct consists of an interosseous part and a meatal part.

Infants with persistent epiphora (tearing) for more than one month should be evaluated by an ophthalmologist to establish the diagnosis and to rule out the other causes of epiphora including glaucoma. Infants with upper respiratory tract infections may develop a transient epiphora due to congestion of the nasal passages.

Initial conservative management consists of daily digital massage over the sac and topical antibiotics. Culture and sensitivity of the conjunctival sac should be performed to rule out conjunctivitis as a cause of epiphora. If the tearing persists, passage of a fine metal probe through the system is needed to make the lacrimal system patent. The procedure is usually performed under general anesthesia.

Successful probing of the pediatric age group depends on early treatment between the ages of three months and two years.[4] Recurrent infection and chronic epiphora tend to cause irreversible scarring of the nasolacrimal passages. Probing is less successful after age three.

If the first probing fails to relieve the epiphora, one should repeat the probing usually within two months. At the time of the second probing, the inferior turbinate should be fractured medially. The purpose of this fracture is to create more space in the area surrounding the inferior meatus. This area is often atretic, imperforate, or blocked by the turbinate.

The fracture is performed with a periosteal elevator the tip of which is placed between the lateral wall of the nose and the turbinate (Figure 2). With steady force, the turbinate is fractured inward and a wider space is created at the inferior meatus.

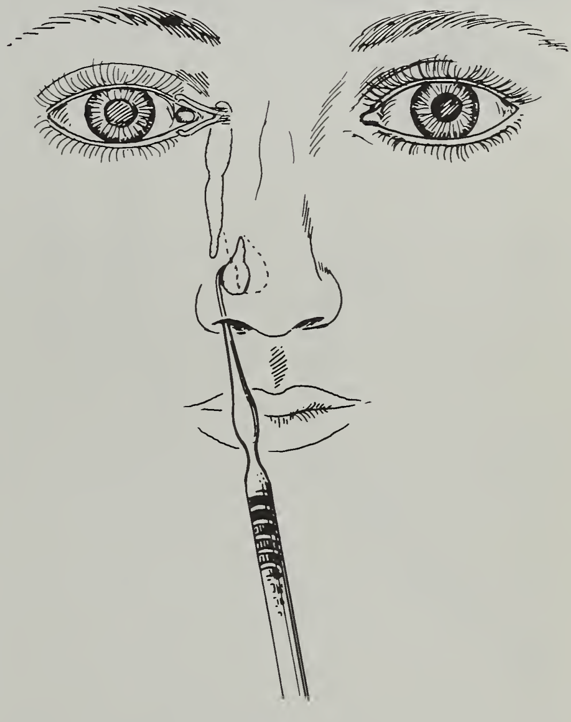

Figure 2
The tip of the periosteal elevator is placed between the lateral wall of the nose and the turbinate.

Silicone intubation plays an important role in the management of persistant nasolacrimal obstruction. If one or two probings are unsuccessful, the child should undergo silicone intubation. The purpose of intubation is to place a temporary (three to six months) stent of the nasolacrimal passages, thereby preventing constriction and allowing re-epithelialization of the passage way. The procedure, first reported fifteen years ago,[5] consists of passing fine silicone tubing swagged on malleable stainless steel probes at either end through the upper and lower canaliculi, the nasolacrimal sac, and duct. The two ends of the tubing are then tied at the exit point beneath the inferior turbinate thus forming a closed loop.

The original technique required grasping the tip of the leading steel probe with a hemostat at the inferior turbinate in order to pull the tubing through the system. A recent improvement consists of a remodeled steel probe with a bulbous tip (Figure 3). By passing a specially designed hook into the region of the inferior turbinate, the bulbous tip is engaged easily and pulled out of the nose. [6] The final appearance of the tubing is illustrated in (Figure 4).

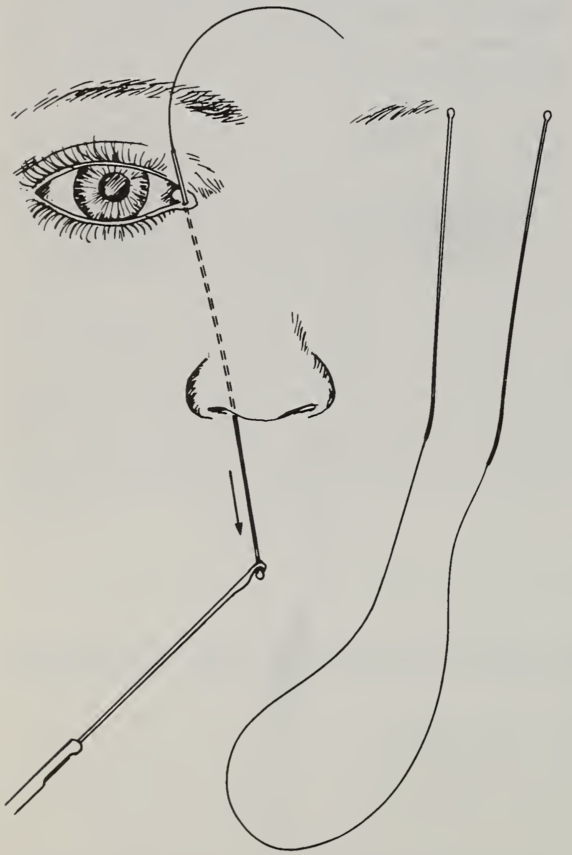

Figure 3
One end of the steel probe has been passed through the lower canaliculus where the bulbous end has been engaged by the special hook.

Children tolerate the tubing very well because it is soft and supple. The complications of silicone intubation include loop retraction and slitting of the canaliculus. These children require regularly scheduled follow-up visits by the ophthalmologist.

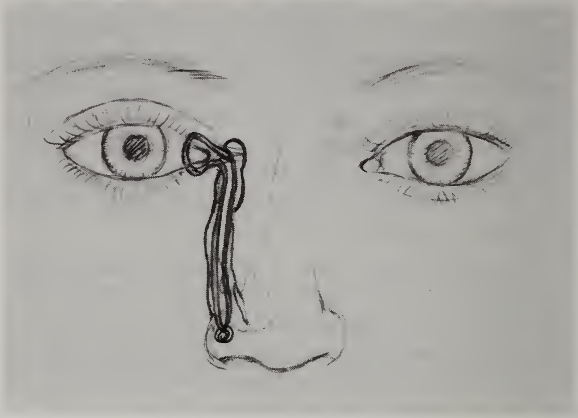

Figure 4
The tubing is seen in final position where it has been passed through the upper and lower canaliculi and tied together in the nasal vestibule to form a closed loop.

If tearing persists after removal of the tubing, a dacryocystorhinostomy should be performed. In this procedure, a rhinostomy is created to allow tears to flow from the canaliculi and sac into the nose, bypassing the obstructed nasolacrimal duct.

In summary, successful treatment of pediatric nasolacrimal obstruction requires early recognition in the neonatal period and a systematic evaluation and treatment. Delay in treatment can result in chronic infections and progressive scarring which reduce the cure rate of nasolacrimal probing.

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Important Advances in Clinical Medicine

Epitomes of Progress—Radiology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in radiology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in radiology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Radiology of the California Medical Association and the summaries were prepared under its direction.

Positron-Emission Tomography of the Heart

Myocardial performance is determined by complex biochemical processes that modulate contractility, electrophysiologic events and cell viability. In vivo assessment of myocardial metabolism has been difficult to accomplish in the past. Until recently, nuclear cardiologists focused on functional imaging such as the evaluation of myocardial blood flow using thallous chloride T1 201 and the study of ventricular function by radionuclide ventriculography. With the recent advent of positron-emission tomography (PET), however, the field of nuclear cardiology enters a new era by imaging regional metabolic processes. This tomographic, three-dimensional approach provides quantitative determination of myocardial tracer distribution because photon attenuation can be accurately corrected for. Positron-emitting isotopes such as fluorine 18, oxygen 15, carbon 11 and nitrogen 13 can be used to label physiologically occurring substrates for the in vivo study of myocardial cell function. The current generation of the PET cameras with high spatial (5 to 10 mm) and dynamic resolution (three to ten seconds per image) provide accurate quantitation of myocardial perfusion and metabolism using validated tracer kinetic models. These characteristics make positron-emission tomography a unique tool for the in vivo assay of biochemistry, which links structure and function in a living organism.

In studying the heart, PET has been used mainly in patients with ischemic heart disease and cardiomyopathy. Regional myocardial blood flow is being evaluated using rubidium chloride Rb 82, ammonia N 13 and water O 15, whereas myocardial substrate metabolism is studied using carbon palmitate C 11 as a tracer for fatty acids and fluorine deoxyglucose F 18 (FDG) as an analog for glucose. Using PET, studies in animals and clinical studies have shown that normal myocardium is characterized by a close match of flow and substrate metabolism because both reflect regional energy demand. The same is true for infarcted myocardium where flow and metabolism are low due to the low perfusion and energy requirements of scar tissue. During ischemia, myocardium cannot oxidize fatty acids but uses glucose anaerobically to meet its basic energy requirements. This regional shift in myocardial metabolism during ischemia can be detected noninvasively by PET as shown in experimental and clinical studies. Therefore, ischemic but viable tissue can be detected noninvasively. Using metabolic tissue characterization, studies of animals showed that PET can predict recovery of function following transient ischemia. Encouraged by these results, PET has been applied to patients with acute myocardial infarction. In a considerable number of patients, viable but compromised tissue was observed in "electrocardiographically infarcted" segments of the left ventricle. The metabolic definition of viable but compromised myocardium early during evolving infarction is most important for salvaging myocardium in view of therapeutic interventions such as thrombolysis and angioplasty. Additionally, in patients with severe coronary

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artery disease and impaired left ventricular function, PET images have been shown to be predictive for the success of a coronary artery bypass procedure. Myocardium with impaired flow but maintained glucose metabolism as estimated by FDG uptake showed functional recovery, while segments with low flow and low metabolism did not recover postoperatively. Because patients with impaired ventricular function have a higher surgical risk, carefully selecting patients for a surgical procedure is clinically important.

In cases of dilated cardiomyopathy, heterogeneous free fatty acid metabolism has been shown by a patchy uptake pattern of carbon palmitate C 11. Furthermore, in patients with severe left ventricular dysfunction, the response of fatty acid metabolism to glucose loading was substantially abnormal. To improve our understanding of the pathophysiology of cardiomyopathy, further research in this area will focus on detecting biochemical defects before deterioration of function occurs. Finally, in patients with Duchenne's muscular dystrophy, there is evidence of a localized myocardial metabolic abnormality that is unique to this disease and can be detected by PET. Again, FDG proved to be a sensitive marker of a regional shift in substrate metabolism.

Positron-emission tomography is still in its infancy, but these initial studies show the potential for metabolic imaging in cardiac disease, especially for such important clinical questions as defining tissue viability in patients with ischemic heart disease. Refining the technique will allow more accurate diagnosis of cardiac disease and better biochemical understanding of the underlying cause.

Markus Schwaiger, M.D.
Los Angeles

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New Developments in Contrast Media

Research of contrast material has recently brought into focus a number of new developments that should have major impacts on the practice of radiology in the near future.

The first of these is the production and clinical testing of low-osmolality media. In general, these new substances take one of two forms: nonionic agents or monoacid dimeric agents. These substances differ from the current ionic media by a decrease in the osmotic pressure of the molecules for a given concentration of iodine. Thus, the new media have a ratio of iodine atom to dissolved particle of 3, whereas current media have a ratio of 1.5. Animal and clinical testing to date indicate that the low-osmolality media are both safer and more comfortable when used for arteriography. While the chemotoxicity of these media is substantially less than that of current media, the data on anaphylactoid effects are still incomplete. Preliminary findings, however, suggest that a significant improvement can be expected in this area also. Currently, only one nonionic agent (metrizamide) is approved for intravascular use in this country. Other nonionic agents are pending approval by the Food and Drug Administration and, when available, will probably become the agents of choice for arteriography. Because they are expected to be considerably more expensive than current ionic media, their overall role in vascular injections remains to be determined. Results of both studies on animals and clinical studies suggest that these media will also confer less toxicity in the subarachnoid space than metrizamide or iophendylate (Pantopaque).

The second development of note concerns the use of perfluorocarbons as contrast agents for ultrasonography. Nonbrominated perfluorocarbons are presently used in humans as oxygen-carrying blood expanders and these substances, when injected as emulsions in both the brominated and nonbrominated forms, appear to combine a low toxicity with effective uptake by reticuloendothelial cells and macrophages, resulting in increased echogenicity of the liver and spleen and experimentally induced tumor rims and myocardial infarcts. Preliminary trials in humans are currently under way and appear highly promising, particularly for enhanced visualization of liver tumors.

The third area of particular interest is the development of contrast agents for magnetic resonance (MR) imaging. Preliminary observations suggest that such agents will dramatically extend the diagnostic value of MR imaging, despite the inherent high-contrast differences obtainable for different tissues with this new technique. Conventional radiographic contrast media produce their effect by high-electron density that absorbs x-rays. MR imaging media, as currently conceived, function by altering local magnetic environments. These paramagnetic substances can be used for intravascular injection, subarachnoid installation or gastrointestinal tract opacification. Data on animals and preliminary data on humans suggest that these compounds can be used effectively in a fashion similar to that of conventional media with very low toxicity anticipated.

Each of these new developments should reach a stage of clinical use within one to three years, with the advent of the new nonionic media for conventional radiography expected within a year.

Elliott C. Lasser M.D.
San Diego

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Computed Tomography of the Spine

Because of its ability to show both soft tissue and bone abnormalities in excellent detail, high-resolution computed tomography (CT) has assumed a dominant role in imaging of the spine, particularly in the lumbar area. Its efficacy in evaluating degenerative disc disease, tumor, trauma, congenital abnormalities and infectious processes has been documented.

More than 95% of lumbar disc herniations occur between L-3 and S-1, so that by scanning these three levels most lumbar disc problems will be encompassed. Contiguous 4- to 5-mm thick axial scans are taken, with additional scans parallel to the discs obtained in some cases. Contiguous scans decrease the likelihood of missing herniated disc fragments that have migrated above or below the disc level and, in addition, make possible sagittal and coronal reformations that are useful in some cases. CT is more accurate than conventional myelography in diagnosing lumbar disc herniation because even lateral and L5-S1 herniations remote from the thecal sac can be readily seen. CT clearly shows central and foraminal spinal stenosis that often plays a significant role in low back syndromes. Abnormalities of the facet joints, which may contribute to low back pain, are also clearly shown. By showing whether root compression is due to focal herniation or bulging of the annulus and whether there is extruded disc material, selection of appropriate therapy such as surgical repair or enzyme injection can be aided. Evaluating the lumbar spine postoperatively with plain CT may be difficult because of surgical distortion. The use of intravenous contrast media in this situation can help distinguish between recurrent disc herniation and scarring.

The role of plain CT in evaluating cervical disc disease is more controversial. Although thin-section CT (1.5- to 2-mm slices) can demonstrate disc herniations and spondylotic changes, diagnostic accuracy is not as high as in the lumbosacral spine. Many authors advise using an intrathecal water-soluble contrast agent to improve the diagnostic accuracy of CT examination of a patient with cervical degenerative disc disease.

The major limitation of plain CT is its inability to show intradural pathologic processes such as tumors. Conventional myelography or CT with intrathecal water-soluble contrast material is indicated when an intradural abnormality is suspected.

Richard Kramer, M.D.
Palto Alto, California

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Radiation Risks in Diagnostic Radiology

The risks of harmful genetic and somatic effects associated with the low doses (a few rads or less) of ionizing radiation received during diagnostic x-ray examinations are too small to be measured. The existence of deleterious effects from much higher doses is irrefutable. The major uncertainty in inferring low-dose risks from dose-effect data obtained at high doses is selecting the type of extrapolation to be used in continuing the dose-effect curve into the low-dose region. Estimates obtained from a no-threshold, straight-line extrapolation of high-dose dose-effect data in animals and, in some instances, humans, to low doses, will be used here. Such estimates are generally considered “worst case,” in that alternative plausible extrapolation schemes lead to lower estimates of risk at low doses.

The genetic risk resides in radiation-induced mutations, generally considered deleterious, which can be passed on to future generations via reproduction. No deleterious genetic (or somatic) effect has ever been documented from natural background radiation. This suggests that if the genetically significant dose, estimated in 1970 to be 0.02 rad per capita per year, remains well below the background radiation dose of 0.1 rad per capita per year at sea level, any additional genetic consequences will neither differ in kind nor exceed in quantity those that have been experienced throughout human history. To obtain a numerical estimate is futile, but taking into account that the dose required to double the spontaneous mutation rate is generally assumed to be 20 to 200 rads, the genetic risk of ionizing radiation from diagnostic x-ray studies would appear to be small. Even so, prudence dictates the maximum possible reduction of human gonadal exposure from diagnostic x-ray studies. To this end, gonadal shielding should be used whenever possible during x-ray procedures on a potentially procreative person.

No direct evidence exists for an association between radiation exposure in utero and harm to an unborn child as a result of a diagnostic x-ray study of the lower abdomen or pelvis of a pregnant woman. However, indirect evidence suggests the possibility of radiogenic birth defects and childhood leukemia. The estimated hypothetical risk of an observable birth defect from a 1-rad in utero dose is 1 to 5 chances in 1,000, whereas the natural incidence rate of birth defects is 40 to 50 per 1,000 live births. Studies in animals indicate that the most critical period for inducing a deformity is during organogenesis, weeks 3 through 7 postconception in humans. Human in utero exposure at high doses from the atomic bomb explosions at Hiroshima and Nagasaki indicates weeks 8 through 15 postconception to be the most critical period for inducing mental retardation. Although not seen in these persons, an increased chance of childhood leukemia for an in utero dose of 1 to 2 rads, from a spontaneous incidence rate of 1 per 3,000 to 1 per 2,000, is suggested by some retrospective epidemiologic studies. These possible risks should be explained to a pregnant patient and documented in her record.

The major concern regarding postnatal exposure to diagnostic x-ray studies is carcinogenesis. The estimated hypothetical lifetime risk per study of cancer developing after a latent period of 10 to 25 years varies from a few chances in a million for a (0.05-rad) two-view chest examination to almost 100 chances in a million for a (3-rad) computed tomographic brain scan. These risks are modest compared with the lifetime risk of dying in an auto accident – 1 in 100 – or contracting cancer spontaneously – 180 in 1,000. The most recent screen-film systems for mammography deliver a mean glandular tissue dose as low as 0.1 rad for a two-breast, two-view study, giving an estimated lifetime risk per study for breast cancer induction after a latent period of 10 to 25 years in a woman aged 40 years or older of no more than a few chances in a million, compared with a natural risk of 1 in 10. The hypothetical risk is down dramatically from a decade ago as a result of the great reduction in dose which fact supports routine screening by age 40 as suggested by the American College of Radiology and the American Cancer Society.

In conclusion, the risks from diagnostic x-ray studies are too small to be measured directly. Estimates of the hypothetical risks show them to be small compared with many risks encountered in day-to-day life in American society. Nonetheless, diagnostic x-radiation must be used prudently and every attempt made to obtain the desired diagnostic information with the minimum radiation dose.

Robert J. Moore, Ph.D.
Loma Linda, California

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Neonatal Intracranial Ultrasonography

Ultrasonography of the neonatal brain is a quick, noninvasive procedure that can be done on fragile neonates in an intensive care nursery without sedation. High-frequency sector-image ultrasound is used to examine the brain through open fontanelles and sutures.

Ultrasonography is most important for diagnosing intracranial hemorrhage due to the combination of immaturity of the germinal matrix that lines the ventricles and immaturity of the lungs and the autoregulatory system. This bleeding is the most common central nervous system (CNS) disorder in premature infants younger than 32 weeks' gestation, occurring in 40% to 60% of such children. Ultrasonography can show subependymal, intraventricular or intracerebral germinal matrix hemorrhage in the acute or the convalescent phase.

Serial examinations are helpful for evaluating the progression of hemorrhage, the development and course of post-hemorrhagic hydrocephalus and, in some cases, the development of periventricular leukomalacia or porencephaly. Ultrasonography of periventricular leukomalacia is now considered more accurate and reliable than computed tomography (CT).

Ultrasonography can be helpful in diagnosing CNS malformations such as congenital hydrocephalus, holoprosencephaly, agenesis of the corpus callosum, hydranencephaly, Dandy-Walker cysts, intracerebral tumors and arteriovenous malformations. CT, angiography or both may be necessary for further characterization.

Ultrasonography is also useful in evaluating term neonatal asphyxia, intrauterine and postnatal CNS infections, head trauma and hemorrhage due to coagulopathy, but CT is usually more definitive in such cases. Cerebellar and subarachnoid hemorrhage is difficult to image with ultrasonography because the cerebellum, the subarachnoid space and clotted blood are all echogenic.

Because the anterior fontanelle is the primary window used to examine the brain, a small fontanelle or overlapping skull bones will limit the quality of the examination. Also, the convexities of the cerebral spaces are not adequately visualized from the anterior fontanelle and, therefore, CT is preferable for examining these areas. Subcutaneous emphysema will also limit or preclude ultrasonography of the brain.

Ultrasonography has proved useful for diagnosing and following various neonatal brain disorders. And it can be used on infants whose condition is too unstable for them to be examined by other methods.

Glenn A. Rouse, M.D.
Loma Linda, California

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Percutaneous Removal of Renal and Ureteral Stones

Percutaneous removal of symptomatic renal and ureteral calculi is now a routine radiologic method that has replaced open stone operations in the vast majority of patients. Not only simple renal pelvic stones but also calyceal, ureteral and staghorn calculi can be managed successfully percutaneously.

Assessing a patient's blood coagulating properties and obtaining informed consent are part of the routine preprocedure workup. Pretreating with antibiotics is important in patients with a history or symptoms of urinary tract infection. Carefully evaluating the patient's renal anatomy based on previously taken intravenous urograms is essential for planning the optimal access route. We do dilations up to 24 or larger French sizes as a single-step procedure using epidural anesthesia. With the aid of fluoroscopy or endoscopy, stones are removed using baskets, grasping forceps or by ultrasonic lithotripsy. A nephrostomy tube is left in the renal pelvis for at least 24 to 48 hours. It is removed when residual stone fragments have been excluded and good antegrade flow of urine has been confirmed. Hospital stays range from three to seven days in uncomplicated cases, but may be as long as two to three weeks in patients with staghorn calculi or many calyceal stones. Close cooperation between the radiologist and urologist has proved helpful for optimal patient management.

The success rate for percutaneous removal of kidney stones is 95% and for removal of ureteral stones it is about 90%. Occasional stone fragments left behind are usually small and asymptomatic.

Major complications occur in less than 5% of patients. They include hemorrhage, which is usually well controlled by blood transfusions and balloon tamponade and rarely requires angiographic embolization. A surgical procedure and nephrectomy are extremely rare complications. Urosepsis occurs in less that 1% of patients and responds readily to antibiotic treatment, provided there is good urinary drainage.

The advantages of percutaneous stone removal over surgical nephrolithotomy or ureterolithotomy are lower morbidity, shorter hospital stay, shorter recovery period and reduced cost.

A new technique for renal stone removal is extracorporeal shock wave lithotripsy. This is a noninvasive method that uses focused ultrasound waves to fragment stones. Its overall success rate approaches 90%. Percutaneous nephrostomy with tract dilatation is the method of choice in the other 10% of patients. Furthermore, percutaneous or retrograde manipulations of the genitourinary tract are required in 8% or 9% of patients who are treated with this technique to relieve ureteral obstruction resulting from passing stone fragments.

Gerhard R. Wittich, M.D.
Eric vanSonnenberg, M.D.
Lee B. Talner, M.D.
San Diego

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Ultrasonography in the Operating Room

Recent technical advances in instrumentation have led to diverse and innovative applications of ultrasonography including its use in the operating room. High-resolution real-time ultrasound units that are portable with scan heads that are relatively small and easily maneuvered have greatly increased the number of uses of sonography in the operating room. The ultrasound probes are placed directly onto the operative field after the probe is enclosed in sterile coverings. In this way, real-time imaging of the operative site provides a surgeon with immediate information before, during or after the operation.

One of the original and now well-established uses of intraoperative ultrasound is in the neurosurgical suite. There are three main applications of intraoperative ultrasonography in neurosurgery: guiding a shunt tube placement, brain biopsy and spinal cord operations. Sonographic monitoring of shunt tube placement allows correct positioning and alleviates possible complications associated with tube placement. Ultrasonography can guide a neurosurgeon in locating a tumor for possible resection and it may be used to evaluate the adequacy of resection after the procedure. In cases in which either an intracerebral or an intraspinal biopsy without resection is necessitated, specialized biopsy guide attachments may be used to allow visualization of the biopsy needle as it is passed into a lesion. Closed brain biopsy improves the rate of tissue recovery and decreases the time of operation. Recently, intraoperative ultrasonography has also been helpful in monitoring the reduction of spinal fractures.

Neurosurgical applications of high resolution intraoperative ultrasonography have been adapted recently for other areas of the body. The development of small high-resolution probes allows their use within the abdomen. The use of ultrasonography to examine the biliary tract and pancreas during a surgical procedure has received the greatest attention. Some of these applications include assessing the gallbladder and biliary system for calculi, locating the common bile duct during difficult explorations, assessing the extent of pancreatitis and detecting and evaluating pancreatic neoplasms. When renal stone resection is required, ultrasonography may be used for guidance. It will show the site of renal calculi and aid a surgeon in avoiding vital structures such as renal arteries and veins during dissection. Sonography has been helpful in detecting intra-abdominal abscesses or in guidance for resection of intra-abdominal tumors. Precision in localization in the abdomen with ultrasound has dramatically reduced the need for extensive surgical exploration, thus avoiding possible complications in critical areas, and it is helpful in assessing the adequacy of a surgical procedure.

Another possible application of intraoperative ultrasonography is in vascular operations to precisely locate pathology before a vessel is open and to check for vascular defects after reconstruction is completed. Ultrasonography can be used in small vessels including during intraoperative assessment of aortocoronary bypass grafts. There are a large number of current and future applications of intraoperative ultrasonography. The acceptance of a particular use will depend on the practical value of ultrasound to reduce operating room time, increase operative safety and ensure the success and efficiency of surgical procedures by improving diagnosis and localization.

John P. McGahan, M.D.
Sacramento, California

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Mammography—Its Use and Risks

Modern mammography is the most accurate method known for evaluating the breasts. It is capable of detecting breast cancer at an earlier, highly curable stage.

Mammography is indicated in a woman who has a breast mass, pain or nipple discharge. It is useful not only in evaluating the site of clinical abnormality but also in surveying the opposite breast. In patients with metastatic disease of unknown origin, mammography is indicated in the search for a primary lesion.

Mammography is the only examination regularly capable of detecting “minimal cancers,” those that are in situ or infiltrating but less than 5 mm in diameter. It is the only imaging method currently acceptable for screening asymptomatic women. The American Cancer Society recommends that every woman have a baseline mammogram between the ages of 35 and 40. Subsequent examinations should be obtained every one to two years, depending on risk factors. At age 50 and older, yearly mammography is recommended.

Although mammography represents the “gold standard” in breast imaging, its limitations should be recognized. First, the accuracy of mammography is limited in women with radiographically dense breasts. A false-negative rate as high as 10% may occur in cases of clinically palpable carcinoma, particularly when the breasts are very dense. If there are clinically suspicious palpable findings, then the lack of specific findings on mammography should not preclude further investigation, including needle aspiration or biopsy. Second, mammography does not always give a specific diagnosis—that is, it may detect a mass but additional procedures, such as ultrasonography to determine if the mass is solid or cystic, and aspiration or biopsy may be necessary to determine whether the mass is benign or malignant. Third, because the breasts of women in their teens and twenties tend to be dense, and because the breast parenchyma is felt to be more sensitive to the effects of irradiation in these patients, mammography should be restricted to cases in which there is a high clinical index of suspicion of malignancy. If there are clinically palpable masses in young women, ultrasound should be considered for the initial examination. If an ultrasonogram does not adequately answer the clinical questions, then mammography should be used.

The radiation doses in mammography are quite low, particularly the doses for screen-film mammography. Based on figures from the Breast Cancer Detection Demonstration Projects carried out throughout the United States in the 1970s and early 1980s, the average breast doses for two-exposure examinations are 0.08 rads for screen-film technique and 0.74 rads for xeroradiographic technique. Because film-screen mammography and xeroradiographic mammography are considered to have similar accuracy, there has been increasing consumer interest in film-screen mammography with its lower dose.

The radiation doses and risks should be taken in perspective. Assuming the maximum acceptable dose of 1 rad for a two-view examination, the theoretical risk of a radiation-induced breast carcinoma is 3.5 cancers per million women per year per rad. In contrast, the natural incidence of breast carcinoma ranges from 800 cases per million women per year at age 40 to 2,500 cases per million women per year at age 65. The theoretical risks of mammography are comparable to those of everyday activities such as driving a car.

Mammography is an extremely accurate and safe method for evaluating the breasts of symptomatic women older than 30 and asymptomatic women older than 35. The benefit-risk ratio of mammography is highly favorable and, it is hoped, will continue to improve as additional technologic innovations result in superior images with lower doses.

Dvora Cyrlak, M.D.
Orange, California

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Noninvasive Doppler Ultrasonography of Carotid Arteries

The development of Doppler ultrasound has greatly enhanced our ability to diagnose a variety of arterial and venous diseases. To date, one of the primary indications for the use of Doppler ultrasound is in investigating cases of possible extracranial carotid artery occlusive disease. This is often referred to as carotid duplex scanning, which is a combination of high-resolution real-time imaging of the carotid arteries with pulsed Doppler wave form and spectral analysis.

In general, patients with a clear-cut history of transient ischemic attacks or reversible ischemic neurologic deficits are studied primarily with selective carotid angiography. Carotid duplex scanning is generally reserved for screening patients who have either an asymptomatic carotid bruit or an unclear history of a transient ischemic attack. In direct comparison studies with selective angiography, carotid duplex scanning has proved to be a reliable technique in showing significant atherosclerotic stenoses at the carotid bifurcation, with accuracies ranging from approximately 85% to 95%. In fact, some authors claim an increased sensitivity for carotid duplex scanning by its ability to detect relatively small plaques that may go undetected by a study such an angiography, which merely shows intraluminal anatomy rather than direct mural lesions.

Specific Doppler criteria for estimating the extent of stenosis have been established by several authors using either a ratio of maximal peak systolic internal carotid flow velocity to maximal common carotid peak systolic flow velocity or using the overall quantitative peak frequency shift obtained within the internal carotid. In persons with normal anatomy, there are both characteristic sounds and wave forms of the internal carotid, external carotid and common carotid arteries. One of the great advantages of carotid duplex scanning is that it combines both anatomic information by virtue of high-resolution real time with the ability to diagnose physiologic disturbances and blood flow with pulsed wave form Doppler analysis. Approximately 10% of carotid bifurcations cannot be adequately imaged with carotid duplex scanning because of a high cervical location of the bifurcation.

One of the major limitations of carotid duplex scanning is that it is operator-dependent. It requires significant experience and commitment to mastering this technique to achieve good results. In experienced hands, however, it is a relatively rapid, noninvasive and inexpensive method of evaluating the carotid bifurcation for significant atheromatous stenoses. To date, the sensitivity for carotid duplex scanning in diagnosing ulcerations is not known, however, because of the inherent tomographic nature of this technique; partial voluming of an irregularly surfaced plaque may lead to misdiagnosis. Because of the ability of carotid duplex scanning to directly image a plaque, in some instances it is possible to characterize the histologic features of a plaque by its sonographic appearance. Calcified plaques produce areas of high-amplitude echoes with acoustic shadowing. Intraplaque hemorrhage has received a great deal of interest in the surgical literature and may be responsible for significant neurologic symptoms, as platelet-aggregate emboli may ensue. Early reports suggest that carotid duplex scanning may have a role in the diagnosis of intraplaque hemorrhage, indicating a biologically unstable plaque even in the absence of a hemodynamically significant stenosis.

When compared with other less invasive techniques such as intravenous digital subtraction angiography, carotid duplex scanning has a number of distinct advantages. First, it is not dependent on patient motion or cardiac output. Second, it is completely noninvasive and does not involve intravenous administration of any contrast media. Third, it is significantly less expensive and often less time consuming. In summary, carotid duplex scanning has proved to be a reliable and clinically useful technique in experienced hands in evaluating significant carotid bifurcation disease.

R. Brooke Jeffrey, M.D.
San Francisco

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Magnetic Resonance Imaging

Experience with the use of magnetic resonance (MR) imaging for clinical diagnosis has been ongoing for more than three years at several centers in the United States and in Great Britain. It is now clear that MR imaging will assume an important place in clinical diagnosis and biomedical research. It has the following distinct advantages: soft tissue contrast resolution far exceeding the limits of computed tomography (CT) and ultrasonography, absence of possible mutagenic effects inherent with ionizing radiation, unequivocal blood pool identification without the need for contrast media and direct imaging in multiple planes (coronal, sagittal, transverse).

These diagnostic advantages have already been recognized for imaging of four parts of the body. MR imaging is the procedure of choice for most purposes in evaluating the central nervous system (CNS), including the spinal cord. Among its advantages are definitely diagnosing leukoencephalopathies such as multiple sclerosis, greater sensitivity for defining brain lesions compared with using CT, improved depiction of lesions in the posterior fossa through sagittal images and freedom from bony artifacts and visualizing the spinal cord without contrast media and discriminating various pathologies within the cord itself.

The natural contrast between the blood pool and cardiovascular structures makes it valuable for cardiovascular imaging. Recent studies have shown its accuracy for the completely noninvasive evaluation of aortic aneurysms and dissections; tumor and bland thrombi within cardiac chambers, arteries and veins; intracardiac and paracardiac masses; presence, site and complications of myocardial infarctions; constrictive pericarditis; hypertrophic cardiomyopathies, and congenital heart disease. Recent reports have indicated its capability for directly visualizing acutely infarcted myocardium and differentiating infarcted from normal myocardial tissue.

High-contrast resolution and multiplanar image acquisition make MR imaging an important modality for imaging of the pelvis, including the diagnosis and staging of prostate, bladder and gynecologic tumors. The sharp discrimination of endometrial and myometrial layers provides the capability to evaluate focal, small tumors and to assess response to oncotherapy and hormonal interventions. Accuracy for the early diagnosis of renal transplant rejection has been shown.

Musculoskeletal applications are now becoming evident: early identification of avascular necrosis, the medullary extent of bone tumors and lumbosacral disc disease. The recent introduction of thinner tomograms (2.5 mm) extends the uses of MR imaging for evaluating disc disease.

The enormous potential of MR imaging has been clearly evident in the first years of clinical operation. The future role is probably underestimated, however, since MR imaging is being compared with other modalities at a time when it is still an immature and rapidly evolving technology.

Charles B. Higgins, M.D.
San Francisco

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Adjuvant Chemotherapy for Breast Cancer

NATIONAL INSTITUTES OF HEALTH

Introduction

In 1985, breast cancer will be diagnosed in approximately 120,000 women; in 90 percent of these women, the disease will apparently be limited to the breast and axillary lymph nodes. Despite advances in early diagnosis and primary treatment with surgery, radiation therapy, or both, more than a third of these patients will develop systemic disease and ultimately die. In the broadest sense, all of these patients are potential candidates for some form of systemic adjuvant therapy.

Adjuvant therapy of breast cancer involves the use of cytotoxic drugs or endocrine therapy after definitive primary therapy. The rationale is to eradicate occult metastatic disease that otherwise would be fatal.

The goal of adjuvant therapy is to significantly prolong survival, while maintaining an acceptable quality of life. Three measures are important in evaluating whether this goal is met by specific treatments:

1. The effect of therapy on overall survival: The length of time a woman survives following a diagnosis of breast cancer.
2. The effect of therapy on disease-free survival: The length of time a woman remains free of any recurrence of disease. Prolonged periods of disease-free survival may be advantageous in their own right, since quality of life is likely to be better before than after relapse. There is also some evidence that longer periods of disease-free survival may translate into better overall survival rates.
3. The effect of therapy on quality of life: In choosing an adjuvant therapy program, potential benefits must be balanced against both short-term and long-term side effects. Also important are the substantial psychological, social, and economic problems women may experience as a result of treatment.

An increasing number of important prognostic variables have been identified that define the natural history of breast cancer. These include well-established factors such as histologic status of axillary lymph nodes, primary tumor size, steroid hormone receptors, menopausal status or age, and histopathology. Assessment of cell differentiation and proliferation, which can be determined by newer techniques, may also be significant. The pathologic status of the axillary lymph nodes remains the single most important prognostic variable, and four lymph node categories have been defined (negative, 1-3 positive nodes, 4-9 postive nodes, 10 or more positive nodes). Since definitions of menopausal status vary widely among clinical trials, age (<50 versus ≥ 50 years) can be substituted as a prognostic variable.

Current adjuvant therapy trials prospectively stratify patients for certain of these prognostic factors, including lymph node status, menopausal status or age, and hormone receptor levels. Variations in local-regional therapy (mastectomy versus conservative surgery plus radiotherapy) may also be important, as less radical surgery is increasingly employed. However, data pertaining to adjuvant therapy have been obtained almost exclusively in patients following mastectomy.

Gains from new or modified adjuvant regimens must be assessed in unbiased prospective clinical trials in which patients are randomly assigned to alternative treatments. In evaluating the results from these studies, it should be recognized that moderate effects on survival may produce significant public health benefits because of the large number of women who may be affected. These effects may be difficult to detect in individual studies due to the limited number of enrolled patients. It is especially difficult to evaluate modest gains that are restricted to subgroups of patients. For this reason, results must be confirmed in multiple studies so that there is consistency in the findings before any therapeutic regimen becomes accepted as standard care.

Advances in adjuvant therapy have come from the combined efforts of health care professionals and thousands of women who have agreed to participate

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

in clinical trials. Since the vast majority of women with breast cancer are not treated in such trials, recommendations regarding the effectiveness of current treatment regimens must be based on periodic interpretations of the available research data.

At the previous Consensus Development Conference held in 1980, a significant benefit of adjuvant chemotherapy on overall survival and disease- free survival could be demonstrated only for premenopausal patients with positive axillary lymph nodes. Since the previous conference, a substantial number of new trials have been initiated, and followup in the older trials has continued. This has resulted in the accumulation of new information regarding the role of adjuvant therapy in the treatment of breast cancer.

To evaluate this new information and to resolve some of these questions, the National Institutes of Health convened a Consensus Development Conference on Adjuvant Chemotherapy for Breast Cancer on September 9-11, 1985.

After listening to a series of presentations by experts in the relevant basic and clinical science areas, a consensus panel composed of representatives from the fields of medical oncology, surgery, radiation therapy, pathology, nursing, epidemiology, biostatistics, family medicine, and the general public considered all of the material presented and agreed on answers to the following questions:

- **Have adjuvant chemotherapy trials in breast cancer demonstrated an increase in survival in any group of patients?**

What is the role of endocrine treatment in the adjuvant therapy of breast cancer?

- **When should women with histologically negative axillary lymph nodes receive adjuvant therapy?**
- **Are there significant adverse effects of adjuvant therapy?**
- **What directions for future research are indicated?**

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1. Have Adjuvant Chemotherapy Trials in Breast Cancer Demonstrated an Increase in Survival in Any Group of Patients?

Premenopausal

Adjuvant chemotherapy has demonstrated a highly significant increase in disease-free survival and a significant reduction in mortality in premenopausal women with histologically positive axillary lymph nodes. Adjuvant chemotherapy can now be considered standard care for these patients. However, while survival advantages are evident, they remain far from ideal, and improvement in the effectiveness of chemotherapy is a goal that must be given highest priority.

Numerous studies have shown that combination chemotherapy is superior to single-agent treatment. Single-agent chemotherapy should be avoided outside a clinical trial. The optimal drug combination has not been defined and is currently the subject of clinical investigation. For patients who do not have access to or who are ineligible for an investigational protocol, the adjuvant chemotherapy combination selected should be one that has demonstrated efficacy in major clinical trials, and the protocol regimen should be followed in detail. Arbitrary dose reductions to circumvent moderate and manageable toxicity may reduce the effectiveness of adjuvant treatment and should not be made.

An optimal duration of adjuvant chemotherapy has not been defined. Some clinical trials have demonstrated that a duration of more than 1 year is not indicated. Regimens of shorter duration (e.g., 6 months) may be equally effective. When primary breast cancer is managed by conservative surgery and irradiation, full doses of adjuvant chemotherapy should be administered.

Postmenopausal

The efficacy of adjuvant chemotherapy for postmenopausal women is less well established. Many adjuvant chemotherapy trials have failed to show an increase in overall survival for postmenopausal patients with histologically positive axillary lymph nodes. However, in a series of trials from one major cooperative group, a modest increase in disease-free and overall survival has been observed. When the sum of the evidence from all randomized trials is examined, the estimate of increase in disease-free and overall survival is small but statistically significant.

Faced with these data, what recommendations can be made for the treatment of postmenopausal, node positive patients? First, survival advantages that accrue from current adjuvant chemotherapy programs must be improved upon through careful clinical research, and when possible, all patients should be offered entry into such trials. If a clinical trial is not available or the patient is ineligible or refuses to participate, the therapeutic decision must balance the toxicity and cost of treatment against its expected benefit. For the woman with both positive nodes and positive hormone receptor levels, this choice is relatively straightforward; tamoxifen has proven effectiveness and minimal toxicity (see question #2). Thus, outside a clinical trial, tamoxifen is preferred in this subset of patients. For patients with positive nodes but negative hormone receptors, the choice is difficult. For some patients and physicians, a small advantage in disease-free and overall survival balanced against toxicity may be worthwhile. In this situation, adjuvant chemotherapy is appropriate, especially if the woman has four or more positive axillary nodes.

When chemotherapy is used in postmenopausal women, the same principles of dose intensity and duration as discussed above for premenopausal women apply.

2. What Is The Role Of Endocrine Treatment In The Adjuvant Therapy Of Breast Cancer?

Decisions regarding adjuvant endocrine therapy should be made with the knowledge of estrogen and progesterone receptor measurements on the primary tumor. Most studies of primary and metastatic breast cancer indicate that the effectiveness of endocrine therapy closely correlates with measured receptor levels. This justifies the use of receptor information in making decisions regarding adjuvant therapy.

Premenopausal

Adjuvant endocrine therapy, either alone or in combination with cytotoxic chemotherapy, has not been shown to result in a survival benefit for premenopausal patients with positive axillary lymph nodes. Thus, there is no justification for the routine use of adjuvant ovarian ablation or tamoxifen in premenopausal patients outside a clinical trial. However, selected studies indicate that either ovarian ablation or tamoxifen may produce therapeutic benefits that justify further clinical investigation. Trials of adjuvant chemotherapy alone versus chemotherapy plus hormonal manipulation are in progress.

Postmenopausal

In postmenopausal patients with hormone receptor positive tumors and positive axillary nodes, numerous studies have demonstrated a highly significant benefit of tamoxifen on disease-free survival. Most of these individual trials have not yet demonstrated a statistically significant increase in survival, but with limited followup time, the trends are in this direction. An overview of all randomized tamoxifen trials shows a highly significant and substantial improvement in overall survival. This benefit of tamoxifen for women older than 50 years of age is even more important because it can be achieved without serious short-term toxicity. Tamoxifen should now be regarded as standard therapy for postmenopausal patients with positive axillary lymph nodes and positive hormone receptor status.

Adjuvant tamoxifen in patients with negative estrogen receptors is generally regarded as ineffective, and a large cooperative group trial in the United States has verified this point. However, data from some European centers suggest that the effects of tamoxifen in patients with negative estrogen receptors may be worthy of further investigation.

The optimal duration of tamoxifen therapy remains to be defined. However, it appears that a longer duration of adjuvant tamoxifen (e.g., at least 2 years) may be more effective than 1 year. Current trials are evaluating the role of tamoxifen given for 4 or more years. There is no evidence to suggest that a dose of tamoxifen higher than 20 mg per day is indicated.

The therapeutic benefit of tamoxifen may correlate with increasing quantity of hormone receptors, but further investigation of this is required. Additionally, tamoxifen may have its greatest benefit in patients with four or more positive nodes. The role of tamoxifen combined with cytotoxic chemotherapy compared with tamoxifen alone for patients with positive axillary lymph nodes and positive hormone receptors remains unresolved and is the subject of current clinical investigation.

3. When Should Women With Histologically Negative Axillary Lymph Nodes Receive Adjuvant Therapy?

Routine administration of adjuvant systemic therapy in women with histologically negative axillary lymph nodes is not recommended at the present time. Unlike some of the other issues addressed in this consensus statement, little progress has been made in this area since the prior consensus meeting. At present, there is not adequate information from randomized clinical trials of adjuvant therapy to demonstrate a significant overall survival benefit for women with negative nodes. Women with negative nodes are encouraged to participate in randomized clinical trials comparing observation with adjuvant therapy.

The prognosis for women with negative axillary lymph nodes is relatively good (65 to 80 percent alive at 10 years). However, some patients with negative nodes are at increased risk for relapse. They may be identified by large tumor size, negative hormone receptors, and cell differentiation pattern, including high degree of anaplasia, high thymidine labeling index, and aneuploidy. For patients at high risk who cannot be entered into an ongoing trial, chemotherapy should be considered, but the decision to institute adjuvant therapy rests with each individual patient and her physician.

4. Are There Significant Adverse Effects Of Adjuvant Therapy?

The acute toxicity from adjuvant chemotherapy is well known and includes varying degrees of leukopenia, nausea and vomiting, fatigue, and hair loss. Amenorrhea and menopausal symptoms frequently occur as a result of cytotoxic therapy and are rarely reversible in women over 40 years of age. Weight gain during treatment is a troublesome effect reported by many women, especially when regimens containing prednisone are used. The acute physical side effects of chemotherapy may be severe, but most can be effectively mitigated. These effects seldom result in hospitalization, and early treatment-related deaths are rare. The psychological, social, and economic costs are significant for the individual patient and her family. Quantitative studies of these issues should be a high priority in future clinical trials.

Major long-term toxicity from chemotherapy is extremely uncommon, although few studies have followed large numbers of patients for long periods of time. In studies from one group at 10 years' followup, 1.7 percent of women who received phenylalanine mustard for 2 years as part of their chemotherapy regimen developed leukemia or a myeloproliferative syndrome (MPS). This compares with a 0.3 percent cumulative incidence of leukemia or MPS for breast cancer patients in the same studies who did not receive chemotherapy. To date, the use of other alkylating agents (e.g., cyclophosphamide) has not resulted in an increased incidence of leukemia.

There is, as yet, no evidence of any greater risk for the development of second solid tumors in patients receiving adjuvant chemotherapy.

Tamoxifen is extremely well tolerated by patients. Side effects, including hot flashes and vaginal dryness, are common and are related to estrogen deprivation. Potential long-term toxicity of tamoxifen is unknown at this time but appears negligible in studies with followup data up to 8 years.

The overall gains in survival achieved by established adjuvant therapy programs for breast cancer significantly outweigh the risk of serious toxicity. Each woman and her physician will need to evaluate the significance of the known and potential side effects of particular regimens when making decisions about the risk-benefit ratio of a specific approach.

5. What Directions For Future Research Are Indicated?

Many issues regarding the use of adjuvant cytotoxic and hormonal therapy of breast cancer remain unresolved. Some are best studied by prospective clinical trials; others require basic research in such disciplines as molecular biology, pathology, pharmacology, human genetics, and cell biology. Issues requiring controlled clinical trials include:

(1) Refinement of staging and prognostic subgroups.

(2) Efficacy of adjuvant chemotherapy and/or endocrine therapy in patients with negative axillary lymph nodes.

(3) Innovative and more effective chemotherapy programs for node positive patients: dose intensification, new combinations of drugs to overcome tumor resistance, timing and scheduling of cytotoxic drugs and hormones, including pre- and perioperative treatment.

(4) Optimal duration of tamoxifen administration.

(5) Accurate assessment of the psychological, social, and economic impact of adjuvant therapy.

(6) Methods to better control the short-term side effects of adjuvant therapy.

(7) Continued assessment of the late effects of adjuvant therapy.

Conclusions

Adjuvant chemotherapy and hormonal therapy are effective treatments for breast cancer patients. While significant advances have been made in the past 5 years, optimal therapy has not been defined for any subset of patients. For this reason, all patients and their physicians are strongly encouraged to participate in controlled clinical trials. Outside the context of a clinical trial and based on the research data presented at the 1985 Consensus Development Conference, the following statements can be made:

- For premenopausal women with positive nodes, regardless of hormone receptor status, treatment with established combination chemotherapy should become standard care.
- For premenopausal patients with negative nodes, adjuvant therapy is not generally recommended. For certain high-risk patients in this group, adjuvant chemotherapy should be considered.
- For postmenopausal women with positive nodes and positive hormone receptor levels, tamoxifen is the treatment of choice.
- For postmenopausal women with positive nodes and negative hormone receptor levels, chemotherapy may be considered but cannot be recommended as standard practice.
- For postmenopausal women with negative nodes, regardless of hormone receptor levels, there is no indication for routine adjuvant treatment. For certain high-risk patients in this group, adjuvant therapy may be considered.

Members of the Consensus Development Panel were: John H. Glick, M.D. (chairman), Philadelphia, PA; Martin D. Abeloff, M.D., Baltimore, MD; Bryon Wm. Brown, Jr., Ph.D., Stanford, Calif.; Charles D. Cobau, M.D., Toledo, Ohio; Bonny Libbey Johnson, R.N., M.S.N., Yale University School of Nursing, West Hartford, CT; Allen S. Lichter, M.D., Ann Arbor, Michigan; Helen B. O'Bannon, Philadelphia, PA; Ruth Ottman, Ph.D., New York, New York; Jose Russo, M.D., Detroit, Michigan; Karl Singer, M.D., Exeter, New Hampshire; Abigail Trafford, U.S. News & World Report, Washington, D.C.; William C. Wood, M.D., Boston, Mass.

Members of the Planning Committee were: Marc E. Lippman, M.D. (chairman), Bethesda, Md.; George P. Canellos, M.D., Boston, Mass.; Jerry Elliott, Bethesda, Md.; John H. Glick, M.D., Philadelphia, PA; Brian J. Lewis, M.D., San Francisco, Calif.; Franco M. Muggia, M.D., New York, New York; Robert E. Wittes, M.D., Bethesda, Md.; Michael J. Bernstein, Bethesda, Md.; Joyce Doherty, Bethesda, Md.

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The Origins of Anesthesia
Parts VI and VII

SHERWIN B. NULAND, M.D.

Part VI
ANNOUNCEMENT AND CONTROVERSY

Although Charles Thomas Jackson has been portrayed up to this point as the accomplished and much respected scientist that he was, it is necessary to describe another aspect of his personality, without knowledge of which it is difficult to understand the foregoing and subsequent events. Jackson was a brilliant eccentric in whom the seed of madness was firmly implanted, and by this time appears to have begun flourishing. Graduated in medicine from Harvard in 1829, he then studied in the hospitals of Paris for two years, at the same time developing an interest in geology and in analytical chemistry. On the return voyage from Paris he made the acquaintance of Samuel F.B. Morse and showed him an electromagnet he was bringing back to Boston; Morse conceived at that instant of the idea that electricity might be the means by which information could be transmitted, and, on arriving home, he began a series of experiments which culminated in the invention of the telegraph. Jackson did not hesitate to claim the credit to himself.

Nor was this the only example of the tendency of his peculiar thought-process to convert a suggestion or an incidental contribution into an outcry that he was the originator of some scientific advance. He even went so far as to make a bold attempt to wrest that reluctant experimentee Alexis St. Martin from William Beaumont. While in Boston with his subject in 1834 Beaumont had asked Jackson to do a chemical analysis of St. Martin's gastric fluid. When the gifted Captain was ordered West by the Army, Jackson attempted to prevent his subject's departure so that he could carry out more experiments, craftily obtaining the signatures of 200 congressmen on a petition describing the importance of his analysis to America and humanity. Had not the Secretary of War rejected the petition, Jackson might have claimed the credit that we now give to William Beaumont as America's first physiologist.

Even as recently as that very year of 1846 Charles Jackson was embroiled in a conflict that he was destined to lose, with Christian Schoenbein, over the German chemist's invention of guncotton. So, Jackson rode into the arena of anesthesia controversy on an experienced charger, carrying a well-used lance. The fact that he had been knocked from his steed in every previous tournament only increased the fever of his obsessed determination to win this one.

In acquiring a patent, Morton had reckoned without the objections of the physicians of the Massachusetts General Hospital and of the dental profession. Warren, in his own words, "checked by the information that an exclusive patent had been taken out, and that no application could be made without the permission of the proprietor," would not allow further use of the agent until the patent restrictions were relaxed. After a three week moratorium, Morton finally agreed to share his secret with the hospital, providing that all information was to be considered confidential. On November 7, etherization resumed with the first painfree amputation, and on November 21 Morton met with two representatives of the hospital, Henry Jacob Bigelow and Oliver Wendell Holmes, and gave the name *Letheon* to sulfuric ether in an attempt to keep up some semblance of concealment. The term was borrowed from the writings of Virgil, who had, as noted in Chapter I, applied it to the restful sleep produced by the tears of the poppy plant.

Meantime, with the U.S. Patent having been issued on November 12, 1846, Morton busied himself with huckstering his potential market. He printed a flurry of notices and circulars, with the purpose of making his discovery known, and to satisfy legal requirements which

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SHERWIN B. NULAND, M.D., Associate Clinical Professor of Surgery, Yale University School of Medicine. Dr. Nuland is Literary Editor of *Connecticut Medicine*. These are Chapters VI and VII of Dr. Nuland's book *The Origins of Anesthesia.*

obliged him to make public announcement of his application for letters patent.

Beginning on November 26, 1846 Morton presented a series of circulars entitled *Morton's Letheon.* The circular went through five editions of increasing size and complexity, the last one appearing in May, 1847. Having by then heard of Letheon's success abroad, which is described later in this narrative, Morton added the subtitle *A Voice from Europe* to this edition.

While the negotiations over rights and confidentiality were taking place, the Harvard physicians had been preparing to tell the news to America's scientific community. On November 3, a brief abstract of the events was read before the American Academy of Arts and Sciences, and then on November 9th a full paper was given at a meeting of the Boston Society of Medical Improvement, by Henry Jacob Bigelow. The paper was printed in the November 18th issue of the Boston Medical and Surgical Journal, the first formal published announcement of the discovery of surgical anesthesia. By then Bigelow had done a number of experiments, and, Warren's moratorium having ended, a few further clinical trials had occurred.

The day after Bigelow's paper appeared, an exact reprint of it was published in the local newsheet, the *Boston Daily Advertiser.*

True to a tradition which has been maintained to our own day by the staff of what is now called the *New England Journal of Medicine,*an editorial commenting on Bigelow's exciting report appeared further back in that issue of the *Boston Medical and Surgical Journal:*

> *Operations without Pain—In the leading article of this day's Journal, by Dr. H.J. Bigelow, the profession will notice that an impression exists here in Boston, that a remarkable discovery has been made. Unlike the farce and trickery of mesmerism, this is based on scientific principles, and is solely in the hands of gentlemen of high professional attainments who make no secret of the matter or manner. To prevent it from being abused and falling into the power of low, evil-minded, irresponsible persons, we are informed that the discoverer has secured a patent, and that means were taken, to have the same security in Europe even before publicity was given to it here. Without further remarks, we cheerfully publish all that has been given us on the subject, and wait with impatience for the decision of the profession in regard to its real value.*

The impatience of the editors must have been matched by the impatience of their correspondents to rush into print with various messages of approval or skepticism. Within days, a letter commenting on patent rights had been received from Dr. J. F. Flagg of Boston, which began a back-and-forth burst between him and Bigelow in subsequent issues. In addition, communications came from several cities describing experiences with and attitudes toward the new discovery.

As noted above, the news spread to Europe quickly and it did so in what was, for that day, not an unusual way. Jacob Bigelow, Henry's father, wrote a letter to his friend Francis Boott of London, telling him of Morton's accomplishment and enclosing a clipping of Bigelow's paper. The letter and the paper were forwarded by Boott to the *Lancet,* which published Bigelow's report in its issue of January 2, 1847, along with a letter from Robert Liston, the brilliantly dextrous and daring Professor of Surgery at University College, London. Bigelow had written to Boott on November 28th, Liston had learned of the letter on Saturday, December 19th, and on the Monday, December 21, 1846, he had carried out the first surgical operation in Europe under ether anesthesia, an amputation through the thigh.

To give ether the ultimate test, Liston had next used it to avulse the nail of a patient's great toe, in his words "one of the most painful operations in surgery." Before beginning to operate, he is reported to have told the assembled students and assistants, "We are going to try a Yankee dodge today, gentlemen, for making men insensible." When the amputation had been completed, the great British surgeon, a member of the same medical faculty that had rejected John Elliotson only 8 years before, could have chosen no more appropriate audience before which to proclaim loudly to all who could hear his booming voice, "This Yankee dodge, gentlemen, beats mesmerism hollow." Sitting quietly among the onlookers was a 19 year-old undergraduate working toward his Baccalaureate degree, Joseph Lister.

Liston's amputation was not, in fact, Europe's first use of ether anesthesia. Boott himself had arranged for a dentist named Robinson to extract a tooth of one Miss Lonsdale in his study at home on the same day, Saturday, December 19, that he communicated the American news to his surgical colleague. Ether caught on quickly in Great Britain. Within a month, James Y. Simpson, Professor of Midwifery at Edinburgh, had used it in childbirth—it was Simpson who, 10 months later, introduced chloroform for the same purpose.

As the world was applauding Morton's triumph, the wily Jackson was not sitting idly by being satisfied with ten percent of the forthcoming profit and very little of the acclaim. Just as his petition to Congress had played down the role of William Beaumont 13 years earlier, he now planned to characterize Morton as someone who had merely acted as his agent in carrying out the technical aspects of the great invention. On November 13, and again on December 1, 1846, he wrote to a friend in Paris, L. Elie de Beaumont, claiming to be the discoverer of anesthesia, the usefulness of which had been amply demonstrated at the Massachusetts General Hospital in consequence of his request to "a dentist of this city" that he so carry out Jackson's instructions.

These letters were read before the Académie des Sciences on January 18, a fact which soon became known to Morton who, realizing the craftiness of his opponent, rapidly set about collecting sworn statements of witnesses. With Wells' trip to Paris, and now Jackson's apparently successful reception by the Académie, Morton felt that his seeming advantage was in imminent danger of being lost. What he did not realize was that Jackson's canny shrewdness was soon to boomerang, as the supposedly sophisticated scientist now proceeded to advance, not his own, but his rival's position, by outsmarting himself.

It came about in the following way: Edward Everett, President of Harvard College, and John Collins Warren, both wishing to put the new discovery and its historical evolution on firm scientific ground, suggested to their academic colleague that he prepare a presentation for the American Academy of Sciences, of which Everett was then Vice-President. In this, Jackson saw an opportunity to legitimize his claims in what was then the outstanding American scientific body. He wrote his presentation in such a way that it not only proclaimed him as the inventor of anesthesia, but implied that he made this claim with the support of Everett and Warren and with the official sanction of the Academy. He sent copies across the sea to Paris, and also to the aptly-named *Boston Daily Advertiser,* which printed the text on March 1, 1847. Although this action made him look better abroad, it exploded in his face at home. Offended at having been used this way, the Academy disavowed the statement, never had it read before one of its meetings, and refused to publish it in its *Transactions.* Jackson suddenly found himself under a cloud of suspicion in the very group he had hoped most to persuade, the American scientific community. Everett's particular mistrust was heightened by the fact that he had been the congressman who, 13 years earlier, had allowed himself to be convinced to present Jackson's petition concerning Beaumont to the Secretary of War.

Now the hostilities had begun in earnest. The rest of Morton's life, and much of the rest of Jackson's, was taken up by a frenzied round of claims, petitions to Congress, crescendos of personal misery, and finally, for each of them, death under tragic circumstances.

But at this point, somehow an oasis of sanity briefly intruded itself into the midst of the controversy's intellectually arid wasteland. Morton, perhaps made more secure in his position by the reverberations of Jackson's misjudgment, managed to write a temperate and lucid brochure containing complete instructions on the administration of ether, which he published in September, 1847. Dedicated to the surgeons of the Massachusetts General Hospital, it has become, in the words of John Fulton and Madeline Stanton, "one of the rarest and most important of Morton's publications." This, the Bigelow and Warren articles, and *Morton's Letheon* are the four basic papers referred to in the introduction to this book. As William Osler put it, they "stand out in the literature of surgical anesthesia as fundamental, and truly epoch-making."

In the Walker Report made to Congress in 1853, in which the government's investigation of the conflicting claims is described, there may be found the details of the dispute that now ensued. But a dusty congressional record does not describe the effects that the controversies had upon their main actors. Jackson went on, promoting himself in various ways and continuing his other scientific work, but never with the effectiveness that had characterized it before. In 1851, he wrote a book entitled *Etherization of Animals and of Man,* which opens with the statement:

> *During the winter of 1841-42 I discovered that the nerves of sensation could be temporarily paralyzed to all sensation of pain by the pulmonary inhalation of the vapor of pure sulfuric ether (oxide and ethyle) mixed with air, and that while the human body was thus affected, that any surgical operation could be performed upon the etherized patient without producing any painful sensations. In 1846 I caused this discovery to be practically exemplified by applying it in surgical operations both in this country and in Europe, where it was also used by my directions.*

In this book, he published the English translation of his 1846 letter to the Académie des Sciences.

Jackson's final work on anesthesia appeared in 1861, in the form of a book of 134 pages, with instructions for the preparation and use of "ether, chloroform and other anesthetic agents by inhalation in surgical operations . . . comprising also a brief history of the discovery of anesthesia."

As the years passed, Charles Jackson, never the most stable of personalities, became more unbalanced. One day in 1873, long after William Morton's death, the aging provocateur came across his late antagonist's grave in the Mount Auburn cemetery, which bears the epitaph:

> *William T.G. Morton.*
> *Inventor and Revealer of Anesthetic Inhalation.*
> *By whom pain in surgery was averted and annulled.*
> *Before whom in all time surgery was agony.*
> *Since whom science has control of pain.*

Reading the words on the stone broke what little was left of the fragile structure of Jackson's reason; he was admitted to the McLean Asylum in Belmont, Massachusetts, where he passed the last 7 years of his life frankly psychotic—he died on August 28, 1880 at the age of 75, his only triumph over his rivals being in terms of longevity.

THE DOWNFALL OF A PUBLIC BENEFACTOR

In response to Jackson's two letters to the Académie des Sciences, Morton, as noted earlier, had entered into the competition with a vengeance, beginning by assembling his testimonials in the way that was usual for the time. He prepared a memoir which was presented to the Académie at its meeting of November 2, 1847, by which time the tide at home was strongly in his favor.

As a result of all of the turmoil, the Hospital Trustees felt called upon to prepare an official history of the controversy. This appeared in the Report of the Board of trustees of the Massachusetts General Hospital, which was issued on January 26, 1848. The history had been prepared by Richard H. Dana, Jr., and was made available to the public in the March 18, 1848 number of *Littell's Living Age,* with Morton's memoir to the Académie appended to it.

The authorities at the Hospital clearly recognized Morton as the true discoverer of ether anesthesia. Several months later he received the following letter.

> *Boston, May 12, 1848*
>
> *Dear Sir:*
>
> *At a meeting of the Board of Trustees of the Massachusetts General Hospital, a few weeks since, it was informally suggested that a limited subscription of one thousand dollars shall be raised for your benefit in acknowledgement of your services in the late ether discovery; no one to be asked to subscribe more than 10 dollars. We consented to act as a committee to receive and apply the proceeds of this subscription. The proposed sum having been obtained, we now have the pleasure of transmitting it to you. We also enclose the subscription book in a casket which accompanies this note. Among its signatures you will find names of not a few of those most distinguished among us for worth and intelligence; and it may be remembered that it is signed by every member of the Board of Trustees.*
>
> *You will, we are sure, highly value this first testimonial, slight as it is, of the gratitude of your fellow-citizens. That you may hereafter receive an adequate national reward is the sincere wish of your obedient servants.*
>
> *Samuel Frothingham*
> *Thomas B. Curtis*

Among the signatories to what was pointedly referred to as "this first testimonial" (James Mumford, in the charming history of American medicine which he wrote in 1903, has italicized the word *first*) were such prominent Bostonians as J.I. Bowditch, J.A. Lowell, G.C. Shattuck, J.C. Warren, Rufus Choate, Daniel Webster, John Homans, R.H. Dana, Jr., and about forty others. It would seem that Morton's victory was complete, but there was a Pyrrhic aspect to it. As he had early revealed the nature of "Letheon" to the physicians of the Hospital so that it might be used by the institution and by other charitable facilities, and as the government of the United States had itself infringed its own patent by the free use of ether during the Mexican War (1846-1848), Morton's legal rights became unenforceable. With his monopoly thus destroyed, some of the licensees who had signed up with him for exclusive sales rights began legal suit. Such litigations were to prove futile for a host of reasons, not the least of which was that Morton had abandoned his dental practice in order to devote all of his money and energies to his claims; he was soon financially ruined, suing and being sued, and finally petitioning Congress for redress. It was this petition which led to the appointment of the Walker Committee and S.B. 210 referred to in an earlier chapter. Disappointed in the outcome of his entreaties to the government, Morton found himself involved in several litiginous actions to test the validity of his patent. Whether badly advised or by now too deeply enmired to care, he chose to sue for infringement a charitable institution, the New York Eye Infirmary. The verdict, later upheld by the U.S. Supreme Court, was against him. The most crippling blow to Morton's pride came the following year, when the medical establishment, which had originally embraced him, had had enough of his contentiousness—at the instigation of Dr. Henry D. Noyes, of the Infirmary staff, he was censured, in scathing language, by the American Medical Association. The following two sentences are taken from their statement, issued on June 24, 1864.

> *Whereas, The said Dr. Morton, by suits brought against charitable medical institutions for infringements of an alleged patent covering all anesthetic agents, not claiming sulfuric ether only, but the state of anesthesia, however produced as his invention, has by this act put himself beyond the pale of an honorable profession and of true labors in the cause of science and humanity therefore*
>
> *Resolved, That the American Medical Association enter their protest against any appropriation to Dr. Morton, on the ground of his unworthy conduct . . .*

Morton was, by this time, dispirited, poverty-stricken, and beyond the point of controlling the maelstrom that was drowning his soul. An article appearing in the June, 1868 issue of the *Atlantic Monthly,* supporting Jackson's position, inflamed his resentment beyond reason. In July, he made yet one more fruitless journey to Washington, but the frustration of its disappointing outcome proved to be too much for him. He arrived back in New York in the midst of a stifling heat wave, feeling dejected and sick. On an impulse, he decided to take his wife, Elizabeth, on a cooling buggy-ride through Central Park. Without warning, he suddenly jerked the horse to a stop, leaped out of the wagon, and plunged his head into the tepid water of the lake. Obviously disturbed, he was urged back into the buggy, but had driven only a short while longer when he precipitously vaulted from the rig, threw his body over a nearby fence, and fell to the ground on the other side, unconscious. Several hours later, the tormented dentist whom William Henry Welch so rightfully called "the least heroic of great discoverers" was dead of a cerebral hemorrhage.

Part VII

THE INTRODUCTION OF CHLOROFORM

Of all those who might be referred to as colorful characters involved in the origins of surgical anesthesia, none more aptly fits the term than James Young Simpson (1811-1870), the seventh child of the village baker of Bathgate, Scotland. In spite of a nature that was basically kind, Simpson retained to the end of his life a forceful directness of approach and a bluntly aggressive certainty of his own rightness that were the despair of his colleagues at the same time that they were clearly the indispensable ingredients of his considerable success. Shortly after receiving his medical degree at Edinburgh in 1832, he realized that midwifery, occupying the least esteemed position among the clinical specialties, had not attracted enough men of high calibre to enable significant advances to be made. He turned his abundant talents toward obtaining as much obstetrical training as he could. After completing the available courses in his own University, he visited hospitals in London and France, rapidly accumulating a wealth of information, largely by collating everything he saw and read. In April, 1836, he published a paper in the *Edinburgh Medical and Surgical Journal,* entitled *The Diseases of the Placenta,* which was received with so much enthusiasm that it had to be translated into German, French, and Italian, instantly bringing recognition to its 25 year old author as one of Europe's authorities on the illnesses of women. Within a few years he was Edinburgh's leading obstetrician and the medical school's outstanding teacher of his specialty.

However, when the Chair of Midwifery became available in 1839, Simpson, although the logical candidate to occupy it, found himself faced with considerable opposition, based principally on his being unmarried, only 28 years of age, and an unconventional, overly ambitious steamengine of a man, a quality particularly obnoxious to the leader of his competitor's forces, the remote, austerely conservative Professor of Surgery, James Syme. Simpson set about to correct what was correctible about himself, and to make good use of what was not. He accomplished both ends of that objective by marrying a young woman whose father was willing to lend him sufficient funds to pursue, as befit the style of his personality, a vigorous campaign for the Chair. Edinburgh professors were elected by the Town Council in those days, and electioneering could be much less subtle than it is today. Simpson's hustling program of self-promotion succeeded by the closest of margins—a single vote made the difference.

Although it reflects no credit on either Simpson or the Edinburgh medical establishment that he had to resort to such blustery means to attain a position he so richly deserved, his appointment proved to be one of the most illustrious in the long and brilliant history of that distinguished medical school. The great contributions which he made to midwifery began with the first years of his professorship. His kinetically forceful and essentially charitable nature enabled his wide-ranging abilities to reach their utmost limits to an estent that is granted to few men. Underlying his accomplishments was a particular philosophy of action which he expressed so well to a group of newly qualified physicians in 1842:

> *"Do not wait for special and favourable circumstances, but work always as if special and favourable circumstances were already actually present. Do not withhold your blows till the iron is heated, but 'strike it till it becomes hot.' Never spare yourselves in your efforts."*

Simpson entered the anesthesia panorama within days of Morton's triumphant news having reached Britain. His next-door neighbor was an Edinburgh surgeon named James Miller who, on December 23, 1846, read to his class of students a letter he had just received from Robert Liston describing his use of ether a few days earlier. Simpson wasted no time—he went immediately to London, where he spoke to Liston and watched him operate on several anesthetized patients. On returning home, he busied himself preparing for the first obstetrical use of ether, which he accomplished on January 19, 1847, the pain-free sleep enabling him to carry out an internal podalic version for a fetus with unengaged head an prolapsed cord. On February 10, 1847, he presented this case and two more before the Obstetrical Society of Edinburgh.

Simpson anticipated that using ether in midwifery would present problems that did not occur in surgical anesthesia, such as the possibility that it might interfere with uterine contractions or do harm to the child or its mother. Moreover, surgical procedures of that day rarely lasted more than a half hour, whereas anesthesia for obstetrics might require a much longer period, a drawback which brought with it not only increased hazards but also the necessity for the medical attendants to contend with greater degrees of ocular irritation and obnoxious smell. There were, in addition, certain unique conditions in Edinburgh that made ether unsafe or unwieldy, such as the fact that so many deliveries were done at home, where candlelight, gaslight, or coal fires might cause explosions. Large volumes of ether being required for prolonged deliveries, a physician would have cause to think twice before embarking on an anesthetic adventure taking place on the upper story of one of Edinburgh's crowded 19th century tenement houses, where dragging a large fluid-filled bottle up numerous flights of winding stairs could tax not only his strength but his ingenuity as well.

Accordingly, Simpson and other physicians who foresaw these problems began to seek other methods of producing anesthesia. What followed is well described by H. Laing Gordon, Simpson's biographer.

In the midst of his now immense daily work he gave all his spare time, often only the midnight hours, to testing upon himself the effect of numerous drugs. With the same courage that had filled Morton he sat down alone, or with Dr. George Keith and Dr. Matthews Duncan, his assistants, to inhale substance after substance, often to the real alarm of the household at 52 Queen Street . . . but the summer of 1847 passed away, and the autumn was commenced before he succeeded in finding any substance which at all fulfilled his requirements . . .

The suggestion to try chloroform first came from a Mr. Waldie, a native of Linlithgowshire, settled in Liverpool as a chemist. It was a 'curious liquid', discovered and described in 1831 by two chemists, Soubeiran and Liebig, simultaneously but independently. In 1835 its chemical composition was first accurately ascertained by Dumas, the famous French chemist. . . . How it finally came to be tried is best described in the words of Simpson's colleague and neighbor, Professor Miller, who used to look in every morning at nine o'clock to see how the enthusiasts had fared in the experiments of the previous evening.

'Late one evening, it was the 4th of November, 1847, on returning home after a weary day's labour, Dr. Simpson with his two friends and assistants, Drs. Keith and Duncan, sat down to their somewhat hazardous work in Dr. Simpson's dining-room. Having inhaled several substances, but without much effect, it occurred to Dr. Simpson to try a ponderous material which he had formerly set aside on a lumber-table and which on account of its great weight he had hitherto regarded as of no likelihood whatever; that happened to be a small bottle of chloroform. It was searched for and recovered from beneath a heap of waste paper. And with each tumbler newly charged, the inhalers resumed their vocation. Immediately an unwonted hilarity seized the party—they became brightened, very happy, and very loquacious—expatiating on the delicious aroma of the new fluid. The conversation was of unusual intelligence, and quite charmed the listeners—some ladies of the family and a naval officer, brother-in-law of Dr. Simpson. But suddenly there was talk of sounds being heard like those of a cotton mill louder and louder; a moment more and then all was quiet—and then crash! On awakening Dr. Simpson's first perception was mental—'This is far stronger and better than ether,' said he to himself. His second was to note that he was prostrate on the floor, and that among his friends about him there was both confusion and alarm. Hearing a noise he turned round and saw Dr. Duncan beneath a chair—his jaw dropped, his eyes staring, his head bent half under him, quite unconscious, and snoring in a most determined and alarming manner. More noise still and much motion. And then his eyes overtook Dr. Keith's feet and legs making valorous attempts to overturn the supper table, or more probably to annihilate everything that was on it. By and by Dr. Simpson having regained his seat, Dr. Duncan having finished his uncomfortable and refreshing slumber, and Dr. Keith having come to an arrangement with the table and its contents, the sederunt was resumed. Each expressed himself delighted with this new agent, and its inhalation was repeated many times that night—one of the ladies gallantly taking her place and turn at the table—until the supply of chloroform was fairly exhausted.'

The lady was Miss Petrie, a niece of Mrs. Simpson's; she folded her arms across her breast as she inhaled the vapor, and fell asleep crying, "I'm an angel! Oh, I'm an angel!"

On November 8, 1847, Simpson made a funnel of a pocket handkerchief, poured half a teaspoon of chloroform into it, and successfully anesthetized his first obstetrical patient. He reported on his conclusions concerning the new agent on November 10, and published the report on November 12. On November 15, he re-issued that *Account*, with a postscript in which he describes having administered chloroform in 50 cases without complication. Within a few days, 4,000 copies of this pamphlet had been sold in the book stalls of Edinburgh, and many thousand more in the succeeding weeks.

By December, 1847, Simpson was prepared to discuss his by-then expanded experience more fully, and to take a stand against resistances to the use of chloroform that were beginning to be expressed. He did this in a pamphlet based upon an address he had given to the Medico—Chirurgical Society of Edinburgh that month. The tone of the pamphlet is not soothing—it is an angry statement directed at his medical colleagues who "insist on mothers continuing to endure, in all their primitive intensity, all the agonies of childbirth, as a proper sacrifice to the conservatism of the doctrine of the desirability of pain." Simpson was determined that the medical community embrace the concept of pain-free delivery, and he felt compelled to respond to every objection that was raised.

One of the fiercest battles that Simpson had to endure was theological; "In sorrow thou shalt bring forth children," states the Bible (Genesis, 3:16), and so stated also the voices of many in the Scottish kirk and elsewhere. To them, blotting out the pain of childbirth was blotting out the will of God. Finally, this opposition had to be met, and Simpson was equal to the task. He engaged his challengers on their own ground, constructing a strong and scholarly argument against them based upon semantics and religious philosophy.

The attitude of skepticism held toward ether by the medical community of Philadelphia pertained also to chloroform. Simpson wrote to Charles D. Meigs, America's foremost obstetrician, and received a reply stating that as of June, 1848, inhalation anesthesia had not yet been used at the Pennsylvania Hospital. Meigs had three objections to its utilization: (1) he considered the pain of labor to be a "desirable, salutory and conservative manifestation of life-force," (2) anesthesia is morally reprehensible, since it produces a drunk-like state (3) chloroform is dangerous.[1] Interestingly, as late as 1851 the second edition of Meigs' classic textbook, *Woman; Her Diseases and Remedies*, carries not a word about ether, chloroform or any type of anesthesia.

'Sad to tell, this highly respected American physician, whose career was marked by so many significant contributions to the understanding of the diseases of women, is today remembered primarily for his two miscalculations: his failure to recognize the value of inhalation anesthesia, and his rejection of Oliver Wendell Holmes' hypothesis about the contagiousness of puerperal fever.

Chloroform anesthesia nevertheless triumphed, in spite of occasional complications and deaths, and in spite also of some continuing philosophical and religious objections. One of the milestones in its acceptance occurred in 1853, when John Snow, the world's first professional anesthesiologist, was summoned to provide his services at the birth of Prince Leopold, Queen Victoria's eighth child. The Sovereign found the experience to be so comforting that she repeated it four years later when her last child the Princess Beatrice, was born.

Chloroform seemed to be safer than ether, and it soon became the anesthetic choice for most operations, and certainly for obstetrics. But before long, chloroform deaths began to be reported, and ether once again became popular. However, there was much to be said for the uncomplicated expediancy of simply pouring chloroform onto a cloth, and what eventually happened was that this method prevailed in Scotland for most of the 19th century, whereas American physicians favored ether poured on a bell-shaped sponge. Meantime, John Snow, concerned that chloroform fatalities were due to the high doses obtained with the Scottish method, developed a sophisticated inhaler with a separate vaporizing chamber and face mask, so that complications might be prevented by controlling the concentration.

Of the major 19th century participants in the origins of anesthesia, James Young Simpson is the only one who was, in the truest sense, a clinical scientist beyond the restricted field of pain-free surgery. He made contributions in the areas of surgical technique and instrumentation, in fetal pathology, and in the understanding of hospital-based infections and hospital administration; he wrote on archaeology and on medical history. Most significantly, he had a vision of what medicine was and what it could be. While still in his twenties he had written, "Possibly even by the concentration of electrical and other lights we may render many parts of the body, if not the whole body, sufficiently diaphanous for the inspection of the practised eye of the physician and surgeon." His vision, however, encompassed more than the technological—he was, with all of his gruff bluntness and restless ambition, first and always a great-hearted healer of the sick, whose beneficent soul knew its own priorities, which are perhaps best stated at the end of his first chloroform publication. Describing the pain and agonies which he had seen averted by the use of his new vapors, he concludes the article by stating what must have been the creed by which he practiced his profession: "I most conscientiously believe that the proud mission of the physician is distinctly two-fold—namely, to alleviate human suffering, as well as preserve human life."

Medical Maxim

What is the source of primum non nocere *("First, do no harm"), a maxim commonly taught to medical students? If it came from Hippocrates, why has it been transmitted in Latin, rather than in Greek?*

David F. Ross
Lexington, Ky.

Harvard classicist Jeffrey Rusten referred this query to a scholar of ancient medicine, Jody Ruben, adjunct assistant professor of classical studies at the University of Pennsylvania. Ruben says the phrase appears to be an abbreviated Latin version of the famous Hippocratic injunction in *Epidemics I*, translated (in the Loeb classical edition): "As to diseases, make a habit of two things—to help, or at least to do no harm."

"As to why the phrase was passed down in Latin rather than Greek," Ruben continues, "it should be remembered that the knowledge of Greek died out in Europe in the Middle Ages. Hippocrates was read and copied in Latin by monks and physicians alike. When the Hippocratic writings were first printed in the fifteenth century, they appeared in Latin translations. The first book of the *Epidemics,* which contains the maxim, was not known in medieval Europe. It was not printed until the sixteenth century, when all seven books of the *Epidemics* were issued in a Latin translation dedicated to Pope Leo X. Down to the mid-nineteenth century the Hippocratic writings were commonly published in Latin, or with the Greek text on one side of the page and Latin on the other."

Ruben has not been able to identify the source of the exact phrasing *primum non nocere.* She suggests it might derive from a longer Latin version, closer to the Greek original, which might have run: "Be sure to practice two principles concerning diseases—*first* to help, then *not to hurt (primum . . . non nocere).*"

—*Harvard Magazine,* November-December, 1985

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The Disruptive Physician

JOHN HORTY, LL.B.

INTRODUCTION

The smooth operation of today's hospital depends upon a professional and courteous relationship among physicians, nurses and other hospital employees involved in patient care, and hospital management. Medical staff officers, committees and department chairmen must carry out complex and detailed responsibilities. The demands on their time are great. One physician's inability to work harmoniously with others can severely disrupt this balance and divert an inordinate amount of valuable physician leadership and hospital management time from vital patient care concerns.

There is a lingering view, especially on the part of individual physicians, that the relationship of the medical staff appointee to the hospital is that of a user of a public place, i.e., that his appointment to the staff entitles him to the use of the hospital's facilities so long as he maintains his license to practice and continues to meet minimally acceptable clinical performance standards in the care of his patients. Personal conduct is not thought to be relevant. Some physicians are still unaccustomed to thinking of themselves as participants with the hospital and its personnel and with other staff physicians in the organized, institutional delivery of care.

Physicians now understand that the hospital's legal responsibility for the quality of patient care embraces the quality of medical care as well, and that the hospital therefore has not only the right, but the duty to establish and enforce standards of competence in physicians who practice in the hospital. The quality of care cannot be divorced from the hospital environment in which it is provided and therefore the hospital must require that physicians, no less than hospital employees and visitors, meet reasonable standards of personal behavior in the hospital.

Those courts which have considered the question have overwhelmingly upheld the authority of the hospital to refuse to appoint or reappoint or to terminate physicians whose behavior has been found to be disruptive of the operation of the hospital.

This article will focus upon identifying the kinds of disruptive behavior that courts have said justifies hospitals' actions in particular cases. The article will discuss when action may be taken, and the appropriate steps to be followed. Finally, the article deals with the importance of appropriate documentation that is needed to build a solid record to defend the hospital's position in the event of a court challenge.

WHAT IS DISRUPTIVE BEHAVIOR?

The Nature of the Problem

The disruptive physician is, by definition, contentious, unreachable and, frequently, litigious. He will not, or cannot, play by the rules. He may be clinically quite competent, often believing himself to be more competent than others on the medical staff. It is not uncommon, however, to find that whatever lies behind his inability to get along with others sometimes or often affects his clinical judgment. He is totally convinced that he is right. Those who would have him behave differently, whether colleagues or not, are seen to be motivated by ignorance, stupidity, jealousy or a desire to destroy him as an economic competitor. They are also believed to be weak and vulnerable. In fact, the objects of his unacceptable behavior are most frequently the weak and vulnerable, not as individuals but by virtue of their positions. He may not openly take on the strong and prestigious but rather seek to undermine and intimidate those who can neither avoid him nor fight back. For these reasons, and regardless of what may cause him to act as he does, he is a formidable person to deal with.

He is not, of course, to be confused with the physician who is merely "different." Those who harbor unorthodox opinions, display unusual tastes or adopt alternative lifestyles may not be to the liking of the majority of physicians on the medical staff or the hospital management or the Board, but as long as they are discharging their

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JOHN HORTY, LL.B., senior partner in the law firm of Horty, Springer and Mattern, P.C., Pittsburgh, Pennsylvania and the author and editor of four publications, *Action-Kit for Hospital Law, Action-Kit for Hospital Trustees, Patient Care Law* and the *Medical Staff Law Manual.*

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responsibilities to the hospital and to their patients and are not fomenting trouble, the hospital has a positive obligation to treat them with the same degree of tolerance and acceptance as it affords the "regulars." It is only when personal idiosyncrasies as expressed in word or deed begin to affect the ability of others to get their jobs done, or impinge on their right to go about their own business free of burdensome harassment, or when they begin to interfere with the physician's own ability to perform well professionally, that action is called for.

Types of Behavior That Signal A Problem

1. Attacks levelled at other appointees to the medical staff which are personal and irrelevant, or go beyond the bounds of fair professional comment.
2. Impertinent and inappropriate comments written (or "cute" illustrations drawn) in patient medical records, or other official documents, impugning the quality of care in the hospital, or attacking particular physicians, nurses or hospital policy.
3. Sexual harassment of nurses or other hospital employees.
4. Non-constructive criticism, addressed to its recipient in such a way as to intimidate, undermine confidence, belittle, or impute stupidity, bad motives or incompetence. The content of the criticism may ostensibly express concern for the patient, implying thereby lesser standards on the part of the person criticized or, in fact, of the hospital itself. Such criticism can be very disarming. To attempt to refute it is to appear to disagree with the standard or, worse, to acknowledge that a lesser standard is acceptable. Furthermore, the physician himself is able to disguise his real motive, which is to hurt, disrupt and harass, behind high-sounding words and his "right" to say whatever he wants in the interest of better patient care.
5. Refusal to accept medical staff assignments, or to participate in committee or departmental affairs on anything but his own terms or to do so in a disruptive manner.
6. Imposing idiosyncratic requirements on nursing staff which have nothing to do with better patient care but serve only to burden the nurses with special techniques and procedures.
7. Rude or abusive conduct to nurses or other hospital employees.
8. Abusive behavior to patients, yelling at them or refusing to listen to their legitimate questions and requests.
9. Negative comments to patients about other physicians, nurses, treatment being given the patient or the operation of the hospital.
10. Threats and/or physical assaults on physicians, employees or others in the hospital or parking lot.

When any one, or a combination of such acts or words, is repeated, the physician has stepped across the line which divides the occasional over-reaction to stress from a course of behavior inimical to the proper operation of the hospital. The court decisions throughout this article illustrate the particular kinds of behavior that have been held to be a reasonable basis upon which a hospital may take action.

WHEN ACTION MAY BE TAKEN

Upon Initial Application

A hospital is not obligated to appoint to its medical staff a physician who has evidenced patterns of disruptive behavior at other hospitals, or during the course of his medical training, either in medical school or as an intern or resident. In this regard, a record of disruptive conduct is no different from a record of substandard clinical performance. The hospital has both the right and the duty to assure itself that new appointees to its medical staff will meet its standards of both professional performance and personal conduct, so long as these standards are reasonably related to the hospital's goals of providing quality medical care and efficient hospital operation. If the hospital has evidence of, or reasonably founded doubts about, an applicant's prior conduct, the applicant has the burden of demonstrating to the hospital's satisfaction that his behavior, as well as his professional performanced, will comport with the hospital's standards.

Denial of staff appointment based on negative reference letters or evaluations has been upheld by the courts. Illustrative of such decisions is the case of *Pick v. Santa Ana-Tustin Community Hospital,* 182 Cal. Rptr. 85 (Cal. Appl. 1982). Dr. Jan Pick applied for medical staff appointment in the Santa Ana-Tustin Community Hospital's psychiatric department. Dr. Pick was denied appointment on the basis that his "manifested personality would create and present a real and substantial danger to the high quality of medical care both to his patients as well as other physicians' patients ... "

A major reason for the adverse action was the negative tone of the letters of reference from former colleagues. The hospital had communicated with the various institutions with which Dr. Pick had been associated, requesting information about him. The replies disclosed that almost invariably Dr. Pick had had difficulty in his dealings with his colleagues and the personnel of the institutions with which he had been associated.

Specifically, the director of the hospital at which Dr. Pick had completed his internship stated in a letter that "[h]e did have some difficulty in his interpersonal relationships particularly in his response to criticism, ability to work with others, and leadership."

The chief of Professional Education of a hospital at which Dr. Pick was a resident for two years, stated that Dr. Pick "performed satisfactorily as a resident but had some personality problems which interferred with his relationship with staff and colleagues. By mutual agreement he transferred to another program for his third year of training." Finally, in two evaluations from hospitals at which Dr. Pick had had privileges, he was rated "below average" with respect to the factors of emotional stability and control and professional relations with patients.

The **California** appeals court, based on this evidence as well as that of specific incidents in which Dr. Pick had caused problems, found that he had not met his "burden of establishing his ability to work with others in a hospital setting in a manner that would assure that high quality medical care would be furnished patients at the hospital." Thus, the denial of staff appointment was upheld.

The **California** Supreme Court upheld a medical staff bylaws provision which required applicants to document "their ability to work with others, with sufficient adequacy to assure the medical staff and the Board of Trustees that any patient treated by them in the hospital will be given a high quality of medical care . . . " but challenged its application by the hospital, in *Miller v. Eisenhower Medical Center,* 614 P.2d 258 (Cal. 1980).

Dr. Miller, a board certified family practitioner, applied for staff appointment to Eisenhower Medical Center. With his application he submitted the names of 25 physicians who could be contacted for recommendations.

The Medical Staff Executive Committee sent letters to all 25 physicians, asking the following questions:

1. "How long have you known this physician?"
2. "What are his professional capabilities?"
3. "Please provide information on his competence as a physician."
4. "Do you feel he would be an asset to our Medical Staff?"
5. "Comments."

Based on the responses to that letter, the Medical Staff Executive Committee recommended that Dr. Miller be denied appointment. Dr. Miller requested a hearing.

At the hearing, a representative for the medical staff executive committee reported that there was no question regarding Dr. Miller's professional capabilities or his competence as a physician, "but that the committee felt that [he] 'came up wanting' with respect to the opinions received on the question of whether he would be an asset to the medical staff."

The court noted that out of 22 responses to the question of whether Dr. Miller would be an asset to the medical staff:

> Approximately 15 were favorable, some enthusiastically so. Of the seven remaining responses, four were clearly unfavorable. Two of these answered simply: "No." One answered: "Very controversial person. Has been disruptive in other situations." One answered: "I have no knowledge of Dr. Miller's plans regarding [Eisenhower Medical Center]. I do have knowledge of several physicians whose feelings are that they would think not."

Four physicians testified on Dr. Miller's behalf at the hearing. Although each was of the opinion that he would be an asset to the medical staff, when asked about his "interpersonal" relationships, their answers indicated that there might be a problem:

> One indicated that he was sometimes "a little impetuous about things which he wanted to be done" concerning staff practices and procedures but that "in the long run most of these ideas were very constructive ideas." Another, responding to a question concerning possible areas of conflict in "interpersonal relationship" with others, stated that although he had heard "rumors" he had himself neither observed nor experienced any such conflicts. A third, characterizing plaintiff as "a controversial person," went on to explain that he had reference to his tendency to express himself quite forcefully and vigorously in the evaluation of the competence of another physician, for example, or the running of a medical institution.

At the conclusion of the hearing, the panel upheld the medical staff executive committee's recommendation to deny appointment. The panel stated that its conclusion was based "upon the determination that sufficient doubt exists concerning Doctor Miller's ability to work with others" as required by the medical staff bylaws.

Dr. Miller appealed to the Board. At the appellate review two additional physicians testified that he

> . . . had a reputation for getting along poorly with his colleagues. One stated that he "creates dissension" and "has relatively few friends in the community," the other that he "does not get along with most members of the medical community." Neither, however, indicated that he had personally had any difficulty working together with plaintiff in the care of patients.

The Board affirmed the recommendation of the medical staff executive committee and denied Dr. Miller's application for appointment.

Dr. Miller went to court seeking to compel the hospital to grant him staff privileges. The trial court denied his petition. Dr. Miller appealed.

One of Dr. Miller's arguments was that the bylaws provision was "so vague and uncertain as to provide a substantial danger of arbitrary or discriminatory application, and it must therefore be held invalid."

The supreme court disagreed. It upheld the bylaw provision, noting

> It cannot be denied that the providing of high quality patient care is, quite properly, the primary concern of all hospital institutions. The governing authority bears the responsibility for assuring that this goal is achieved to the greatest extent possible, and its decisions relating to medical staff must take into account all factors which have a legitimate relationship to it. We are not prepared to say that an applicant's ability to work with other medical personnel in the hospital setting may not have a clear effect on the level of patient care provided.

But, the supreme court narrowly interpreted the bylaw provision as follows:

> [T]he bylaw here in question . . . must in our view be read to demand that there be a demonstratable nexus between the applicant's ability to 'work with' others and the effect of that ability on the quality of patient care provided. What is required, in short, is that an applicant demonstrate that he has the ability to 'work with' others in the hospital environment in a manner which, in the words of the bylaw, will insure 'that any patient treated by [him] in the hospital will be given a high quality of medical care.'

The court gave the hospital two options. It could appoint Dr. Miller to its staff or it could conduct "further administrative proceedings directed to the assessment of plaintiff's qualifications for admission to its medical staff *in light of a proper interpretation of its Standards."*

Eisenhower Medical Center never had to make the choice. As reported in a California newspaper, Dr. Miller was sentenced to 25 years in prison for conspiring to murder his wife.

This is the only case of which we are aware, that requires the hospital to show that the physician's conduct would have a negative effect on the patient care provided by the physician. To a great extent the court's interpretation arose out of the narrow language of the bylaw provision itself: "Only physicians and dentists . . . who can document . . . their ability to work with others, with sufficient adequacy to assure the Medical Staff and the Board of Trustees that *any patient treated by them in the hospital will be given a high quality of medical care."* The decision highlights the paramount importance of careful bylaws drafting, for the standard to be applied must be stated more broadly.

In *Hagan v. Osteopathic General Hospital of Rhode Island,* 232 A.2d 596 (R.I. 1967), a physician who was denied appointment to the staff of the hospital at which he completed his internship sought a court order compelling the hospital to appoint him. Although the trial court conducted a thorough evidentiary hearing, it ultimately decided that, because the hospital was a private corporation, its decision was not subject to judicial review and dismissed the complaint. The physician appealed.

On review, the supreme court of **Rhode Island** elected to consider the doctor's chances of winning on the merits. If he had none, it would not be necessary for the court to rule on the question of whether the court had the power of judicial review.

The physician's principal contention was that the hospital decision was arbitrary, capricious and unreasonable. The trial court did not so find, and in reviewing and upholding that determination, the supreme court held:

> [T]he trial justice found that defendant trustees had rejected plaintiff's applications " *** because of a personality clash with the hospital administrator in the first instance, . . . and because it was felt by the Board of Trustees that he might be a potential disruptive force in the hospital . . . "
>
> The record is replete with evidence of incidents involving personality clashes from which the trial justice could draw the inference that the Trustees were motivated in their decision on each application by a desire to avoid the creation of a hospital ambience not conducive to the best interests of the sick and injured for whose welfare the hospital existed . . .
>
> When the motivating circumstances of a decision made to achieve a valid purpose bear a reasonable relationship to the purpose intended to be achieved by the decision, such decision will not be disturbed by the courts as being arbitrary, capricious or unreasonable within the meaning of the equal protection guarantee. [Citation omitted.]

The case of *Sosa v. Board of Managers of the Val Verde Memorial Hospital,* 437 F.2d 173 (5th Cir. 1971) further supports the proposition that the board of a public hospital may require staff appointees to meet criteria which include appropriate behavior as well as professional competence. The *Sosa* decision is an important statement of the responsibility of hospitals generally and it has frequently been cited in court opinions from many jurisdictions.

Dr. Sosa had applied for appointment on several occasions, and each time had been turned down by the board without being told the reason. He finally filed suit. Finding that he had not been granted due process, the court enjoined the hospital from refusing his application, but permitted the hospital to impose such limitations as its bylaws would permit.

Before the hospital had a chance to act, Dr. Sosa was back in court demanding that the hospital be held in contempt of the court's order. The hospital moved for a stay of the order pending appeal, but the court denied it and ordered Dr. Sosa's admission with specified privileges while the hospital processed his application for additional privileges. Three days later the court expanded the privileges it had ordered to include major and minor surgery, "the same as every other Staff physician." The hospital appealed.

On appeal, the court reinstated the original order covering minor privileges, and ordered the hospital to complete the processing of Dr. Sosa's application within 30 days and transmit its report to the court. The hospital board complied and at the conclusion of its hearing voted unanimously to deny Dr. Sosa any additional privileges. It also voted unanimously that,

> . . . had the court not ordered Dr. Sosa placed on the Staff, based on the testimony received *** it is the decision of the Board that Dr. Sosa's application for Medical Staff privileges be denied for the following reasons:
>
> 1. Abandonment of obstetrical patients while in active labor, who had previously received pre-natal care from Dr. Sosa, because they could not pay his bill

2. Lack of knowledge of basic minor surgery techniques, basic operating procedures, and instrument identification and use, sufficient to jeopardize patient care

3. Unstable physical demeanor, visible indecision and nervousness in operating room situations, likely to jeopardize helpless and unconscious patients

4. Unstable and potentially dangerous mental condition manifested by numerous examples of anger and fits of rage, toward patients, fellow physicians, and support personnel

5. Unsatisfactory reports from references listed in Dr. Sosa's application

6. Itinerant medical practice patterns since completing his formal medical education

7. Pleas of guilty for two felony charges

8. Suspension of medical license by Texas and Michigan Boards of Medical Examiners

9. Violation of five of the ten Principles of Medical Ethics.

Because the trial court had had no chance to review the procedural aspects of the hospital board hearing, the court remanded the case for a determination of whether the hearing had been *procedurally* adequate. In doing so, however, it provided guidelines for the trial court on the substantive issues.

Noting that the bylaws state only that medical staff appointees be graduates of approved schools, licensed to practice in Texas, and practicing within a reasonable distance of the hospital, the court acknowledged that Dr. Sosa met these "paper qualifications." It further observed, however, that this does not confer "an unconditional right to hospital privileges if the Hospital Board chooses to exact additional standards reasonably related to the operation of the hospital." The board had authorized the Credentials Committee to inquire into character, qualifications, and standing in the community. The court said,

> We think the stated factors used by the Credentials Committee of the Medical Staff to evaluate staff applicants are reasonable. This court had recently indicated that staff appointments may be constitutionally refused if the refusal is based upon 'any reasonable basis, such as the professional and ethical qualifications of the physicians or the common good of the public and the Hospital ...' Admittedly, standards such as 'character, qualifications and standing' are very general, but this court recognizes that in the area of personal fitness for medical staff privileges precise standards are difficult if not impossible to articulate ... The subjectives of selection simply cannot be minutely codified. The governing board of a hospital must therefore be given great latitude in prescribing the necessary qualifications for potential applicants ... So long as the hearing process gives notice of the particular charges of incompetency and ethical fallibilities, we need not exact a precis of the standard in codified form.

The court was clearly indicating that it considered the substantive issues settled in favor of the hospital when it sent the case back to the trial court "to determine the propriety of the procedures used by the Board in making its latest determination. If the Board's procedures do comport with due process requirements, then its determination to deny staff privileges to Dr. Sosa should be affirmed."

The same conclusion was reached by the Fifth Circuit Court of Appeals in *Laje v. R.E. Thomason General Hospital,* 564 F.2d 1159 (5th Cir. 1977). In that case a **Texas** hospital refused to grant staff privileges to a psychiatrist on the grounds of incompetence and insubordination. The physician had been employed by the hospital as clinical director of psychiatry but was summarily discharged for "insubordination" with eleven months to go on his contract. He then applied for staff privileges, but the hospital postponed definitive action on his request and refused to give him a hearing. Dr. Laje obtained an order from the federal district court directing the hospital board to provide him a hearing.

At the hearing, allegations of both incompetence and insubordination were considered. On the insubordination issue, there was testimony to the effect that the doctor had refused to cooperate in treating drug addicts, had employed restraints in violation of hospital policy, and had been unable to get along with the medical director. After the hospital board decided to deny his application, the physician went back to court. The district court held that the board's decision was not supported by substantial evidence and ordered the hospital to grant him privileges, but the order was stayed pending the hospital's appeal.

When the circuit court reviewed the record, it reversed the district court, saying,

> As for the substantiality of the evidence upon which the board's adverse decision was based, we find that the record contains sufficient evidence to support the denial of privileges. The evidence presented at the hearing related to the level of Dr. Laje's professional competence and his ability to function smoothly in the hospital setting. Thus, the board complied with this Court's guideline ... that 'in exercising its board discretion the board must refuse staff applicants only for those matters which are reasonably related to the operation of the hospital.'

Once again, an appellate court recognized smooth working relationships as a proper, and enforceable, requirement of medical staff appointees.

The court of appeals of **Washington** reached a similar conclusion in *Rao v. Auburn General Hospital,* 573 P.2d 834 (Wash. App. 1978). Although the factual basis on which Dr. Rao's requests for privileges was denied is not set forth in the court's opinion in great detail, a footnote indicates that her "personality" played some part in the decision, and the court held that,

> In its own interest and in the public interest, a hospital does have the discretionary right to exclude doctors from staff privileges, whether based on the doctor's lack of proficiency or *upon the concern that the doctor has a personality which will be detrimental to the working of the hospital.* [Emphasis added.]

These judicial decisions clearly recognize that if there is evidence that a physician's behavior might impede the orderly operation of the hospital or affect the proper discharge of his responsibilities to the hospital or to his patients, the hospital may deny his application for appointment to the medical staff regardless of his technical medical competence.

Denial of Reappointment

Every court which has reviewed a hospital's denial of reappointment due to the physician's disruptive behavior has found misconduct to be a sufficient basis for the decision not to reappoint.

In *Ladenheim v. Union County Hospital District,* 394 N.E.2d 770 (Ill. App. 1979), the medical staff of Union County Hospital, a public hospital, recommended approval of Dr. Ladenheim's reappointment, even though he had exhibited uncooperative behavior in the past. The board of directors refused to go along with the recommendation and decided not to reappoint him. Dr. Ladenheim sued and won a restraining order, giving him access to the hospital's facilities, until the hospital held a hearing to determine his eligibility for reappointment.

That hearing was initiated by a five-page notice which set forth 16 general charges of unprofessional conduct and listed 21 separate incidents that supported the charges. At the hearing, the charges were substantiated by evidence which the court summarized in these words:

> After hearing the evidence, the Credentials Committee (who acted as the hearing panel) concluded that the following allegations were true:
>
> —In August, 1976, during a dispute over administrative procedures, [Dr. Ladenheim] told a physical therapist that she had body odor and repeated the conversation to two other hospital employees.
>
> —In March, 1976, after receiving a bill for laboratory work done on a patient not sufficiently identified to allow direct billing of the patient, [Dr. Ladenheim] returned the bill with a note indicating that the business office staff was stupid.
>
> —In January, 1976, he refused to admit a patient to Union County Hospital, telling a relative of the patient that he was "mad at the hospital."
>
> —He refused to complete a medical planning form titled "Discharge Planning" on a nursing home patient, writing "you dreamer" across the space provided for his input.
>
> —On several occasions he made disparaging remarks to or refused to work with a particular nurse, and in one instance told her that an emergency room patient could go to another hospital "or go to hell" as far as he was concerned, because the patient was receiving medical assistance from welfare.
>
> —He refused to bring his criticisms of the nursing staff to the director of nursing, circumventing her entirely in favor of complaining to the hospital administrator. In addition, he indicated to another staff member that it was useless to request the nursing director's assistance, because she would not take any action.
>
> —In June of 1975 and February of 1976, he refused nurses' requests to come to the emergency room to attend patients. He left standing orders that no nurse was to institute cardiopulmonary resuscitation on any of his patients until receiving orders from him or another doctor.

When it faced that array of incidents and evidence, the Credentials Committee voted against reappointing Dr. Ladenheim. Appeals to the hospital's Joint Conference Committee, the full medical staff, the board of directors, the Union County Circuit Court and the Illinois Court of Appeals followed and failed.

The latter court's conclusion strongly endorsed the hospital's decision as having a valid basis in the evidence:

> [T]he record is replete with evidence of appellant's inability to work effectively with other members of the hospital staff, and it is apparent that this personality problem was the principle issue before the Credentials Committee . . .
>
> Clearly, appellant's ability to work with other members of the hospital staff was in itself sufficient grounds to deny him staff privileges . . .
>
> . . . [W]e believe that a rational connection exists between the hearing and review provisions of the Bylaws, which were followed and afforded to appellant, and the Hospital District's insurance of professional and ethical qualifications of the staff physicians for the good of both the hospital and its patients.

In *Robbins v. Ong,* 452 F.Supp. 116 (S.D. Ga. 1978), the hospital denied Dr. Robbins' reappointment because of his disruptive behavior. Dr. Robbins' conduct included throwing a scrub brush outside the operating room, abusive shouting, interruption of a nurses' training session, verbal attacks on hospital employees, and disregard for hospital policy. Dr. Robbins asked the court to grant an injunction to restrain the hospital from revoking or refusing to renew his privileges. In its opinion denying Dr. Robbins' request, the federal district court described the personality of the disruptive physician and the position of the courts in these cases as follows:

> At the hearing before this Court, patients of the plaintiff and physicians attested to his ability as a doctor. His competence is not in issue. *What is in issue is the turmoil and disruption he has brought to the Liberty County Hospital for years. Apparently he is imbued with the idea that where Dr. Robbins sits, there is the head of the table. Rules are for others, not him. The trouble with the conception is that the Hospital is a*

> *public institution, not his private domain.* It is operated by the Authority, a though which he apparently cannot tolerate.
>
> Personalities are at the heart of the problem . . . It is for the Authority to decide whether personality differences are detrimental to the efficient operation of the hospital. This Court should not substitute its evaluation for that of the authority. [Emphasis added]

In *Yarnell v. Sisters of St. Francis Health Services,* 446 N.E.2d 359 (Ind. App. 1983), the **Indiana** appellate court held that disruptive behavior is a sufficient reason to exclude a physician from a hospital, and that the governing board of the hospital is ultimately responsible for the medical staff appointment process.

In January 1981, the Medical Board (the equivalent of the medical staff executive committee in other hospitals) recommended that Dr. Yarnell, an anesthesiologist, not be reappointed to the staff. A hearing was held according to the bylaws. The hearing committee recommended that Dr. Yarnell be reappointed. The Medical Board then changed its recommendation and also recommended to the Governing Board that Dr. Yarnell be reappointed.

The administrator and executive director opposed Dr. Yarnell's reappointment because he was "threatening and abusive of medical staff personnel, and he was generally disruptive of hospital procedures." After receiving this information the governing board notified Dr. Yarnell that another hearing would be held.

Before the second hearing could be held, Dr. Yarnell sued asking for an injunction to prevent the hospital from taking his staff appointment away and subjecting him to the hearing. The trial court dismissed the suit. Dr. Yarnell appealed.

On appeal, Dr. Yarnell argued that the governing board was bound by the Medical Board's favorable recommendation because of a bylaws provision that said that once a recommendation was received from the Medical Board, *"the Governing Board shall appoint"* the individual with specific privileges. The court disagreed, stating:

> Even though the Governing Board has delegated some of its authority, it still remains ultimately responsible for the efficient operation of the Hospital and the maintenance of high standards of professional care imposed by the Hospital bylaws and statute.

The court also disagreed with Dr. Yarnell's contention that the administrator and executive director had acted with prejudice or malice toward him. The court found that they were merely carrying out their duties on behalf of the hospital. On the other hand, the court noted that the evidence indicated that Dr. Yarnell was a disruptive physician, which provided the hospital sufficient reason to deny him staff privileges.

The *Yarnell* decision is especially important because it reaffirms the authority of the governing board, and it *specifically endorses the involvement of hospital management in the reappointment process.*

The **New Hampshire** Supreme Court upheld a denial of reappointment based upon trial court findings that Dr. Bricker had been "a disruptive force" in the hospital. In *Bricker v. Sceva Speare Memorial Hospital,* 281 A.2d 589 (N.H. 1971), the supreme court held that the hospital board's decision was justified, to "preserve and protect the hospital," in light of its "duty to maintain the hospital for service to all the public."

The Supreme Court of **Hawaii** also recognized the legitimacy of "personality" factors in withholding or terminating medical staff appointments, even though that precise issue was not before the court in *Silver v. Castle Memorial Hospital,* 497 P.2d 564 (Haw. 1972).

It is thus apparent that the disruptive physician has no more reason than the incompetent physician to assume the automatic renewal of his appointment to the medical staff. The hospital may, and should, consider and act upon displays of unacceptable behavior when it determines whether or not to reappoint physicians to the medical staff.

Action for Disruption During the Term of Appointment

Personal conduct, no less than clinical performance, may pose such a threat to the safety and well-being of patients, *and efficiency of the hospital operation itself,* as to warrant the imposition of a *summary* suspension. There is no reason to distinguish between poor clinical performance and poor behavior or conduct in taking action during the term of a physician's appointment.

Any single episode of disruptive behavior which, taken alone, might not appear to be sufficiently serious to warrant revocation of privileges, may be but the latest in a series of similar episodes which render the physician's continued presence in the hospital no longer tolerable. The hospital need not wait until reappointment time to act, nor should it be reluctant to initiate proceedings because it did not deny reappointment on the basis of the previous episodes. No court has yet held, nor is one likely to, that by failing to take action at some particular point in a course of continuing disruptive conduct the hospital has, in effect, waived earlier incidents and is therefore foreclosed from considering them in revoking privileges.

That point was made clear by the **Colorado** Court of Appeals in *Leonard v. Board of Directors, Prowers County Hospital District,* 673 P.2d 1019 (Colo. App. 1983) when it rejected a physician's claim that the use of a 1977 complaint against him in a hearing held in 1980 "prove[d] the board's bias against him because since 1977 the board had annually renewed [his] staff privileges." The court found that the doctor's " 'stale charge' argument" was without merit, citing the **Pennsylvania** Superior Court in *Miller v. Indiana Hospital,* 419 A.2d 1191 (Pa. Super. 1980), which held:

> Merely reappointing appellant annually to the staff did not indicate an intention on the part of the hospital to ignore the cumulative effect of appellant's prior

> misconduct. Appellant has neither alleged nor proven any reliance upon the assumption that the actions of the hospital constituted a waiver. It was therefore proper for the hospital committees to consider prior misconduct which may not have been so egregious in any one year as to warrant denial of appointment, but the cumulative effect of which called for appellant's dismissal from the staff.

The hospital board decided to revoke Dr. Leonard's staff appointment and clinical privileges after Dr. Leonard refused to meet with the Board "to discuss with them a certain medical procedure involving possible malpractice" performed by Dr. Leonard. In its opinion, the court related the events subsequent to his refusal:

> After having received several letters from the hospital board and its attorney requesting more open communications, plaintiff wrote the hospital board a letter characterizing the board's request for information as a 'kangaroo court proceeding.' In addition, plaintiff sent a written memorandum to the board's attorney advising him to contact plaintiff's attorney if he wished any further information. This memorandum depicted a set of lips on the posterior of a nude figure. The letter and memorandum described were the key events which led the board, following its 1980 renewal of plaintiff's staff membership, to change its position and commence proceedings against plaintiff to terminate his staff privileges.
>
> In March 1980, the hospital board requested the executive committee of the medical staff to take corrective action against plaintiff. The executive committee met, studied the charges, discussed them with plaintiff, and then among themselves voted that the appropriate corrective action was to send a letter of reprimand to plaintiff. The executive committee then issued the written reprimand.
>
> In April of 1980 the hospital board voted to reject the executive committee's corrective action against the plaintiff. They voted instead to revoke permanently plaintiff's privileges and removed him from the medical staff.
>
> Dr. Leonard requested and was granted a hearing in compliance with the hospital's bylaws. The seven member hearing panel supported the board's decision to revoke Dr. Leonard's privileges. An appellate review was conducted by the board itself and by the Joint Conference Committee composed half of board members and half of medical staff appointees. Again, the board's decision was affirmed.

Dr. Leonard sued, claiming that the hospital board could terminate his privileges only upon the recommendation of the Medical Executive Committee. Since the Medical Executive Committee had "issued a written reprimand to [Dr. Leonard]; thus implicitly 'recommending' non-suspension of [his] privileges" Dr. Leonard argued that the board was not empowered to terminate his privileges. The court disagreed, stating, "There is no provision in the bylaws which expressly constrains the hospital board to act in accord with the MEC's recommendation."

Dr. Leonard also argued that the hospital board and the hearing committee "was disqualified by reason of bias and prejudice." Rejecting Dr. Leonard's claim, the court said:

> Here, the withdrawal of the hospital board members for reason of alleged bias would make it impossible to decide the question of plaintiff's medical staff privileges since the board is the only body empowered under the bylaws to make such decision.
>
> * * * *
>
> The evidence in the record is simply insufficient to support plaintiff's notion that members of the hospital board or of its independent hearing committee were biased or unfairly prejudiced against plaintiff, so as to require disqualification. Plaintiff's lengthy list of the alleged biases of various members of the board and of the board as a whole amounts to little more than a grasping of straws.

The court ended its opinion with a statement recognizing that hospitals' main concern in these cases is patient safety and that courts ought to permit hospitals latitude in dealing with them:

> Finally, flexibility is required in the application of due process in hospital cases . . . Due process in hospital cases is a concept which dictates that physician problems be resolved with minimal procedural complications because of the hospital's interest in patient safety. [Citations omitted.]

The *Leonard* case was not the first time the **Colorado** appeals court decided a suit brought by a physician whose medical staff appointment was terminated due to disruptive behavior. A few years earlier, in *Even v. Longmont United Hospital Association,* 629 P.2d 1100 (Colo. App. 1981), that court upheld the hospital's decision to terminate the privileges of an anesthesiologist because of "unprofessional conduct," consisting of "strong hostility, an uncontrolled temper and actions which intimidated personnel of the hospital working with him in the operating and recovery rooms of the hospital to such a degree as to disrupt the normal functioning of the operating and recovery rooms of the hospital with real and potential danger to the care of patients in the hospital."

The court rejected the physician's claim that he was denied due process in light of the fact that "he received 33 days advance notice of and participated fully in an evidentiary hearing before the board."

The court also specifically approved of the use of the standard of "unprofessional conduct," stating:

> Further, although Dr. Even's technical competence as an anesthesiologist was not challenged, the standard of 'unprofessional conduct' utilized here was sufficiently objective to guard against arbitrary and unreasonable application. And applying this standard to include disruptive personal and professional relationships with other operating room personnel, as

> was done here, was not unreasonable . . . The findings of the board were supported by competent evidence, and are binding on review. [Citations omitted.]

One final note on the *Evens* case. When the hospital board issued the findings based on the evidence presented at the hearing, it included the following statement:

> That there is evidence that the conduct of Leroy M. Even may be based upon physical or emotional problems which could respond to medical treatment.

Dr. Even's privileges were terminated, "with the proviso that if evidence should be subsequently presented that the condition leading to these findings had been corrected, a reapplication on his part would be considered."

That is appropriate. Disruptive behavior may often be the result or symptom of a physical or emotional impairment. When that is the case, the hospital should encourage the physician to seek the professional help he needs. If the condition that caused the disruptive behavior is corrected, and the hospital board, management and medical staff leadership are convinced that neither patient care nor the operation of the hospital would suffer if the physician returned, the physician can be given the opportunity to do so.

Cipriotti v. Board of Directors of Northridge, 196 Cal. Rptr. 367 (Cal. App. 1983) is another case in which the physician's disruptive behavior was apparently caused by emotional problems and drug use. The pattern of behavior which led to Dr. Cipriotti's suspension was summarized by the California court of appeals as follows:

> These incidents were not isolated behavior problems. For example, in 1978, petitioner entered inappropriate and disrespectful comments on a patient's chart; on one occasion he improperly circumvented Hospital's admitting procedure in order to admit a patient; for several months in 1978 he retained duplicate insurance payments rather than promptly returning them to patients; in mid-1978, he initially refused to attend a mandatory court hearing for one of his patients; and in January 1979, he admitted a patient whom he knew to be under the care of another physician without notifying the other physician.
>
> Other incidents were more serious. They included: (1) giving a violent emergency patient 100 milligrams of Thorazine (a powerful tranquilizer), which was four times the recommended dose. This was done by pouring off the medicine into an uncalibrated container and in an unmeasured amount: (2) improperly supplying Hospital employees dangerous controlled substances, in one case to a person with a mental disorder which was such that the giving of the drugs to such a person was in the opinion of one staff member like "pouring gasoline on a fire"; (3) condoning use of controlled drugs at parties at his residence and attended by Hospital employees including the psychiatric unit employees; (4) displaying a hashish pipe and condoning the use of controlled substances and dangerous drugs in the presence of employees and a patient of the psychiatric unit; and (5) having parties where unit workers smoked marijuana and used drugs which resulted in the tardiness at work of the employees the following mornings. Petitioner's attitude towards this conduct, as indicated at the judicial review hearing, was that it was not "horrible," presumably meaning that it was in petitioner's point of view unimportant.

Prior to his summary suspension, Dr. Cipriotti, a psychiatrist, was placed on temporary probation by the Department of Psychology for failing to attend mandatory patient staffing conferences and failing to prepare histories and progress notes. He was also required to resume psychotherapy himself with his own psychiatrist.

According to the court Dr. Cipriotti's own psychiatrist characterized his symptoms as "neurotic" and his conduct as "rebellion towards authority"; "immature and self-destructive"; and "ill considered and improvident." One month after the temporary probation ended two other incidents occurred. One involved poor management of a violent patient; the other an unethical referral of a patient. Those incidents prompted the summary suspension. The court upheld the suspension, finding that the decision was based on substantial evidence and the hearing afforded Dr. Cipriotti following the suspension had been fair.

The court's conclusion in the *Cipriotti* opinion contains an especially strong statement that the hospital's duty owed to prospective patients, compels the conclusion that hospitals must have a "high standard of professional standard," or risk exposure to the risk of lawsuits brought by those patients against the hospital for negligence in selection of its medical staff. "Revocation or other similar disciplinary proceedings," said the court, "are not for the purpose of punishment, but primarily to protect the public."

Each individual act of disruption may not in itself be significant enough to warrant disciplinary action. It is the pattern of conduct of the disruptive physician rather than individual instances of disruption that is significant. It is, therefore, important when each instance of unacceptable conduct or behavior occurs, to make a written record of the event and of the action taken.

However, the record should not be a catalog of ineffective oral warnings. Where it seems necessary, written letters of reprimand, or suspensions for a period of a week or two for each incident, depending upon the incident's severity, should be used. This will not only aid in correcting the physician's conduct, but also builds a record that indicates a pattern of disruption as well as a continuing attempt to deal with it in a positive manner.

The failure to take some action when an individual disruptive act occurs leads outside observers, like courts, to the conclusion that the disruption was of little significance in the operation of the hospital. A good example of such a situation is *McMillan v. Anchorage Community Hospital,* 646 P.2d 857 (Alaska 1982).

In 1975, while Dr. McMillan, an anesthesiologist who had been appointed to the medical staff of Anchorage Community Hospital two years earlier, was out of state taking board certification examinations, the chief executive officer sent a letter to his home summarily suspending his privileges because of his disruptive behavior.

According to the court, "the charge of disruptiveness was based on a series of problems and incidents occurring from 1973 through 1975 between McMillan and the nursing staff, other staff physicians, a nurse anesthetist, and the relatives of several patients."

Dr. McMillan requested and was granted a hearing. The Hearing Committee upheld the suspension and the Board affirmed the Hearing Committee's decision. Dr. McMillan sued.

The case eventually reached the Alaska Supreme Court to decide "whether the circumstances leading to the charge of disruptiveness against McMillan were sufficient for summary suspension of his privileges."

Dr. McMillan argued that "under the terms of the medical staff bylaws and the requirements of due process, summary suspension is only proper where there is some emergency or immediate need for suspension in the best interests of patient care."

Although the court found that "there need not always be evidence of a clear connection between disruptive conduct and any immediate threat to patient care in order to justify suspension of staff privileges on the basis of disruptive conduct," it concluded that in this case the summary suspension was not justified.

The conclusion was based, in part, on the testimony of the chief executive officer at the hospital hearing. The court included that testimony in a footnote to its opinion:

> Webb [the chief executive officer] was asked why, if McMillan's disruptive behavior had gone on for over two years, Webb had not instituted suspension proceedings or summarily suspended McMillan sooner. He replied in part:
>
> Well, several reasons. In 1974 when he went on vacation he'd given an ultimatum that if this nurse stayed he would not return. I thought he would keep his word. Was disappointed when he came back. He was still a member of the Clinic. We were still trying to work out the differences, and at times things were not in a constant high-level of irritation. There were highs and lows, and hoping that things would work out, that everything would get along fine, we went along with it. Another thing, it's sort of like having a burr under the saddle or a sore on your arm. You sort of get accustomed to it and it isn't until the burr is gone and the sore is relieved that you realize how damn good it feels without it, and that is sort of the case that occurred this Fall.
>
> And when I thought he was going to take his shingle someplace else and hang it up, I thought beautiful, we can get someone in here we can depend on. We can schedule our cases in advance and know that we are going to have coverage on those days to handle those patients and we'll do it all without a lot of hard feelings or a lot of irritation, and the day that I got this letter that he planned on being back to practice here I immediately sent the copy of the letter to him summarily suspending his privileges. This—the time that he was off anyway would not have caused him any loss of cases should we not be able to prove our case, and it felt so damn good to have that burr gone from under the saddle that I felt that was the time and place to cut it off was when he was gone and we had coverage rather than waiting until he came back . . .
>
> Later Webb was asked:
>
> Are you telling me that you had a continuing problem that went on and you finally decided that it would be pleasanter to get rid of it?
>
> [Webb:] Yes.

The court concluded that the hospital hadn't established a sufficient basis for suspending Dr. McMillan summarily:

> The incidents which occurred immediately prior to McMillan's suspension were scheduling disruptions caused by McMillan during the medical malpractice crisis, a conversation with a nurse anesthetist during which McMillan suggested that the nurse anesthetist should think twice before coming to work at the hospital, and a heated encounter with another nurse supervisor. There is absolutely no evidence indicating that any of these incidents resulted in adverse patient care.
>
> The reasons which the hospital gave for taking immediate action also do not justify summary suspension. A desire to avoid the burden of the more time consuming section 1 proceedings [which required an investigation and hearing *prior* to suspension of privileges] is not sufficient justification. The claim that operating room conditions would become materially worse upon McMillan's return is also insufficient justification, because it does not appear that McMillan's prior actions had resulted in any imminent threat to or actual adverse impact on patient care. We conclude that McMillan has established that the evidence did not justify his summary suspension.
>
> In spite of all its protestations that McMillan's activities were not in the best interests of patient care, the hospital's reasons seem to have more to do with wanting to get rid of 'a burr under the saddle' or a 'personality that [would] not change' than they do with concerns for patient care. Even giving extreme deference to the hospital's need to act quickly in the best interests of patient care, this is not sufficient justification for summary suspension.

Although the court agreed Dr. McMillan that the summary suspension was not justified, it refused to order the hospital to reinstate him, as he had requested. Instead, the court ordered the hospital to compensate Dr. McMillan for his loss of income from the date of the summary suspension until the time that he was properly suspended following the hearing.

In *Kiracofe v. Reid Memorial Hospital,* 461 N.E.2d 1134 (Ind. App. 1984), a physician was summarily suspended because of his clinical judgment in treating a patient. His appointment was later terminated based not only upon that incident, but upon a history replete with disciplinary actions for disruptive behavior, including:

> refusal to explain orders to nurses, abusive behavior towards nurses who questioned his orders, entering inappropriate and defamatory statements in medical records, failure to complete medical records in a timely fashion, and giving orders which were inappropriate and potentially harmful. These incidents led the medical staff to require Kiracofe to obtain counseling, to his censure, and to a recommendation to suspend his privileges.
>
> Kiracofe's privileges were placed on probation by the medical staff in January, 1981. His privileges were limited and his work was subject to scrutiny by the officers of the medical staff and the family practice session. Additionally, the terms of his probation also required Kiracofe to undergo psychiatric counseling and evaluation from a psychiatrist approved by the Executive Committee of the medical staff.

In its review of the summary suspension, the Executive Committee also reviewed a chronology of his past behavior, which was considered in making its recommendation to terminate the physician's appointment. The court upheld the propriety of reliance upon this past record. And the court rejected the argument that the committees and Board were unduly prejudicial because of "petty personality conflicts."

Termination of appointment on the basis of a pattern of disruptive behavior has also been upheld by appellate courts in **Arizona,** *Peterson v. Tucson General Hospital, Inc.,* 559 P.2d 186 (Ariz. App. 1976) and **Michigan,** *Anderson v. Board of Trustees of Caro Community Hospital,* 159 N.W.2d 347 (Mich. App. 1968). It has been held as a valid basis for termination of participation of two oral surgeons in a hospital's emergency room rotation in **New Jersey,** *Grodjesk v. Jersey City Medical Center,* 343 A.2d 489 (N.J. Super. 1975), and for termination of a thoracic surgeon's employment by the Veteran's Administration, *Gilbert v. Johnson,* 419 F.Supp. 859 (N.D. Ga. 1976).

The supreme court of **Kentucky** did take the opposite point of view in *McElhinney v. William Booth Memorial Hospital,* 544 S.W.2d 216 (Ky. 1976). But here the court determined that the hospital had set its standard for revoking privileges in the bylaws and then attempted to use a stricter standard in the case. In it, a surgeon's staff privileges were revoked for *"gross unethical or moral misconduct,"* the language used in the medical staff bylaws. [Emphasis added.]

The evidence against him was catalogued by the court as follows:

> We glean from the evidence that appellant probably incurred the wrath of the hospital administration when he insisted that an investigation be made of the complaint of one of his surgical patients that a supervisory nurse had made lesbian overtures to her. [He] also complained about the dust levels in the operating room. He entered a collision course with a physician named Richfield, who was the chief of pathology at the hospital, complain[ing] that Richfield was too frequently unavailable to read frozen section slides and left too much responsibility to assistants who were not pathologists . . . He entered criticisms of professional performance and hospital procedure upon the records . . .

The court concluded its summary of the evidence with the observation that the doctor "was doubtless somewhat abrasive to others in his insistence upon what he conceived to be required standards of care."

In finding for the physician, the court determined that his conduct did not violate the "standards" for termination expressed in the bylaws, saying,

> . . . The express standards, vague though they be, do not condemn criticisms relating to treatment of patients or hospital practice nor do they proscribe inability to get along with some doctors or hospital personnel.

It is plain from the court's language that it perceived the hospital's action as an attempt to jettison "an especially competent, dedicated and busy surgeon whose prime concern is the welfare of his patients and the improvement of hospital conditions" for essentially petty reasons. Given that the bylaw provisions were couched in very general terms and, more importantly, specified that the offending conduct be "gross," it is not surprising that the court found them to be a standard not met by the evidence and not sufficiently definite in "proscribing the conduct" on which the physician's termination was grounded.

It is essential to note, that the court expressed "no opinion as to the validity of a reasonably definite standard undertaking to proscribe and make a cause of termination inability to work in harmony with other personnel." The court also observed that none of the charges against the doctor "affect patient care." Thus, the case cannot be read as a rejection of the hospital's right to terminate a staff appointment for disruptive behavior.

Laying A Good Foundation

A hospital has the implicit corporate authority to act in cases of disruption in order to fulfill its purpose of providing quality medical and hospital care in an atmosphere conducive to it, even without language in its bylaws specifying that staff appointments are conditioned on the cooperation and proper behavior of the appointees.

However, good bylaws language can be very helpful in court for it makes the court aware of the standard the hospital will apply. However that is not the only reason for adopting clear and careful language. Careful language will certainly serve the purpose of putting all medical staff appointees on notice that "ability to work with others" is a criterion they are required to meet to be eligible for initial medical staff appointment and for continued appointment. The hospital should place appropriate language in both the corporate bylaws and those of the medical staff.

Corporate Bylaws

The experience of many hospitals in dealing with disruptive physicians leads to the conclusion that disciplinary action for disruptive behavior more properly rests with the board and management than with the medical staff. Frequently, incidents and manifestations of the problem are experienced most directly and continually by hospital personnel, not other physicians.

By reason of their specialties or their schedules, many physicians on the medical staff do not regularly encounter their colleagues in day-to-day practice in the hospital. Furthermore, if the intolerable conduct is directed primarily at nurses or other hospital personnel, other medical staff appointees may be personally unaware of it. Because the rest of the medical staff does not see and feel the effects itself, it is often blind, or indifferent to its seriousness. As a result, it does not act, or procrastinates or minimizes the problem, which heightens the effect with respect to hospital personnel.

Even where the behavior affects other physicians, the medical staff structure may not be the ideal vehicle for dealing with it. For one thing, those who are not personally affected may see it as nothing but a "personality conflict" and may not wish to deal with it for fear of setting a precedent of conduct for other of their peers or themselves. It is often phrased as "everybody has a bad day" or "there, but by the grace of God, go I" or "we'll be next."

On the other hand, it may in fact be a matter between two physicians, in which case there is danger that supporters will rally behind each and turn a disciplinary matter into a power struggle. And, in addition to their vulnerability to counter-attacks by invective or change in referral patterns, there is a reluctance to act on the part of physicians which stems from their view of their relationship to the hospital as purely individual without a sense of identification with hospital operation. If the issue is not one of clinical competence it is not, in their view, any of their business. For any and all of these reasons, if discipline is left only to the medical staff, it may never occur, or may be undertaken in a highly charged atmosphere which is unduly traumatic and virtually invites litigation.

The hospital should exercise jurisdiction over these matters, and can do so by providing the initiative and the appropriate procedures in its own bylaws. This focuses attention on the problem where it is being felt, in the management and employees. The board will relieve the medical staff of a responsibility for which it has neither the taste nor the experience, and will give recognition to the fact that the problem is one between the hospital and the individual physician, not between him and his colleagues.

It also makes it apparent to hospital employees that the board is aware of its obligation to run an efficient and effective hospital. This does not preclude the medical staff from making a recommendation to the Board, but clearly provides the hospital the option to assume control in a situation in which the medical staff is reluctant to take action. When a physician understands that he is accountable directly to the board for his personal conduct or behavior, the hospital may have less difficulty in changing behavior in an informal way than when the physician perceives that he would be bending to the wishes of his colleagues in matters that he considers none of their business.

Therefore, to give the hospital appropriate tools, the following language should be included in the hospital's corporate bylaws:

> The Board shall appoint a medical staff operating in accordance with these bylaws and those bylaws of the medical staff approved by the Board. The medical staff shall operate as an integral part of the hospital corporation and, through its department chairmen, committees and officers, shall be responsible and accountable to the Board for the discharge of those duties and responsibilities delegated to it by the Board from time to time. The Board specifically reserves the authority to take any direct action it deems appropriate with respect to any individual appointed to the medical staff or given clinical privileges or the right to practice in the hospital. Action taken by the Board in such matters may, but need not, follow the procedures outlined in the medical staff bylaws. Any Board action that would result in a reduction of clinical privileges, suspension of clinical privileges for a month or more, revocation of staff appointment or denial of reappointment shall entitle the affected individual to a hearing and appeal as outlined in the medical staff bylaws except that (a) the members of the Hearing Panel shall be appointed by the Chairman of the Board and (b) at the conclusion of the hearing, the Committee's recommendation and report shall be sent directly to the Board.

Medical Staff Bylaws

The medical staff also has delegated responsibility for undertaking disciplinary action in these matters. This delegation is in addition to the hospital's ability to act in the absence of a staff committee recommendation.

The hospital must be sure that the medical staff bylaws do not contain any language similar to that quoted in the

McElhinney and *Miller v. Eisenhower Medical Center* cases, *supra,* which narrowly limits the grounds for suspension or termination, or a refusal to appoint. Narrowly written bylaw provisions may prejudice the hospital's ability to terminate a physician for conduct which would, in the absence of such self-limiting language, be a proper and legally supportable basis for taking action. The following language should be placed in the medical staff bylaws under "Qualifications for Appointment":

> Appointment to the medical staff is a privilege which shall be extended only to professionally competent individuals who continuously meet the qualifications, standards and requirements set forth in these bylaws and in such policies as are adopted from time to time by the Board. Only physicians and oral surgeons (and podiatrists) who can document their background, experience, training and demonstrated competence, their adherence to the ethics of their profession, their good reputation and character and their ability to work harmoniously with others sufficiently to convince the hospital that all patients treated by them in the hospital will receive quality care and that the hospital and its medical staff will be able to operate in an orderly manner shall be qualified for appointment to the medical staff. The word "character" is intended to include the applicant's mental and emotional stability.

This language will give medical staff leadership the proper tools to take action.

ACTION TO BE TAKEN

Notwithstanding the difficulty of doing so, it is obviously important to deal with disruptive problems at the earliest possible moment. Whatever hope there may be of moderating disturbing behavior will best be realized by addressing it at once, before attitudes have hardened and while it is still possible to treat the matter as one of minor dimensions. Certainly this is so with respect to the physician himself. But it is also the case for the hospital. If the physician knows that what he is doing is unacceptable, and that the hospital is prepared to act on it, it is not unreasonable to hope that the problem may be contained. An even if it is not, the fact that it was recognized and addressed early will strengthen the hospital's case for having to do something about it as it continues to escalate.

Just as surely as it is wise to attempt to curb conduct or behavior problems in their earliest appearance, it is also wise to do so with the utmost caution. It is a delicate matter to take issue with the expression of an individual's personality, and to do so in a heavy-handed, accusatory way is to invite resentment and possible retaliation or to make the disruptive physician a martyr to his colleagues. The initial approach should be undertaken as a friendly gesture, designed to be helpful to the physician, but at the same time firm in making it clear that it is more than a difference of opinion; that is, that if the behavior continues, more formal action will have to be taken to stop it. The participants should be as few in number as possible, not only to minimize the doctor's feeling that he has been the object of widespread discussion, but also to limit the targets of any attempts at retaliation.

Because personal retaliation is so strong a possibility, it is important to involve legal counsel in the matter at the outset. His detachment from the immediate scene permits him to evaluate and guide the likely course of action. He can help to moderate the tone and the terms of the initial approach, counsel those who must act as to what they might expect, and help to prevent the effort from collapsing by attempts to intimidate. He should first satisfy himself that there is a genuine reason for concern, and that it is not a petty issue, or a cover for some other reasons for "going after" the physician.

The attorney should also consider the vulnerability of those who must initiate action. If the "proper" person to deal with the matter within the organizational structure of the medical staff is a physician with a long history of disagreement with the problem doctor, or one who is his economic competitor, another medical staff leader should be found. Whoever undertakes the job is likely to incur the wrath of the disruptive physician and should be prepared, emotionally and factually, for the possibility of counter-charges, and, perhaps, the stirring up of malpractice litigation. He should have the assistance of hospital counsel, and the full backing of the hospital, from the beginning.

If proper action is not taken, the disruptive impact of the behavior may instead fester, provoking gossip and rancor. And, there is a potential for hospital liability to the disruptive physician that could be far greater than any consequences arising out of the physician's appeal from revocation of appointment if public discussion replaces private action.

In *Thompson v. Grays Harbor Community Hospital,* 675 P.2d 239 (Wash. App. 1983), a pediatrician sued the hospital and some individual physicians and nurses, for "tortious interference" with her medical practice. She claimed her practice had dropped off because they "intentionally" demeaned her to her patients. The defense countered that she lost patients because of her abrasive personality. The trial court had set aside a jury verdict in her favor, but the appellate court reversed, restoring the verdict.

The appellate court specifically disagreed with the following comments contained in the trial judge's order that had set aside the verdict:

> Dr. Thompson became convinced that the defendant doctors and hospital personnel were committing the tort of intentional interference with her pediatric practice and in consequence started this lawsuit.
>
> As a caveat, it is apparent that the serving of Summons

> and complaint on the manner defendants was not regarded by the defendants and their families and friends as demonstrating esteem and affection. Likewise the deposing of most of the 42 witnesses could not be calculated to induce community or personal harmony. It would be an understatement to say that Dr. Thompson, a strong personality, was controversial. However sincere and intense Dr. Thompson may have been in her suspicions and beliefs about the activities of the defendants, all of the parties were in court in an expensive 14-day lawsuit because Plaintiff undertook this legal action. The defendants were not in court by their own choice.
>
> The intensity of Plaintiff's approach was reflected by her subpoenaing defendant doctors to be in court every day of a lengthy trial without regard for their patients or practice.
>
> * * * *
>
> In a nutshell, the plaintiff's problem throughout this lawsuit has been to find evidence or actionable words or acts, to substantiate her deeply held suspicions and accusations. It would appear to the court that Dr. Thompson was sincere, intense, and accusatory. Being sincere, intense, and accusatory is not a substitute for evidence . . .
>
> It would appear to this court that the jury verdict against the hospital was based on passion, prejudice, intensity and the accusatory activity of Plaintiff; . . .

But the hospital's posture was *defensive:*

> [T]he defendants presented substantial evidence indicating that the conduct of the defendants toward the plaintiff was routine, and in fact in some instances especially careful and restrained; that the plaintiff had characteristics that caused some patients to like her and others to dislike her. There was evidence of practices and procedures employed by Dr. Thompson that were somewhat different from the usual concept in such matters, i.e., (1) an aversion to the use of cow's milk for children; (2) that she delivered a baby in her office under less than desirable circumstances; (3) that she referred to another doctor in unflattering language, i.e., "a butcher;" (4) that she was difficult in her behavior to hospital employees; and (5) that she exhibited displays of temper.

Some of these would have been a strong basis in support of hospital action against Dr. Thompson, but as defenses of "truth" and "privilege" in this type of lawsuit, the court held they fell short. Instead of the hospital's initiating action, testimony indicated that the following events occurred:

> Various parents testified they took their children to the emergency room at Grays Harbor Community Hospital and asked for Dr. Thompson. According to the witnesses the hospital staff made them wait longer, told them falsely Dr. Thompson was not available and made some disparaging remarks about her. In some cases the parents were encouraged to have their children treated by the house physician instead of by Dr. Thompson. Some of the parents followed this advice.

One parent testified:

> A. Well, the nurse said that it wasn't the best choice I could have made, that Dr. Thompson—it would cost me $40 for her just simply to walk across the parking lot before she ever looked at my son . . .
>
> Just for her to walk across the parking lot she will charge, and then when the babies were born she ran all kinds of unnecessary tests on them, evidently—she never actually came out and said it but the indication was for the monetary compensation that she would get from this.
>
> Q. Did the nurse every suggest that you should not choose Dr. Thompson as a pediatrician?
>
> A. Yes, she did.
>
> Q. And how did she do this?
>
> A. She said—I was kind of in awe hearing all this, and she said, you know, you don't have to take Dr. Thompson. You can have Dr. Koeniger look at the baby while he's in the hospital, you know, I can get him to look at him for you and then when you get out you can take him to your regular general practitioner.
>
> So after hearing all this I said okay, well maybe that's what I better do.
>
> She said, would you like me to call downstairs and have the name changed on the papers from Doctor Thompson to Doctor Koeniger? I said well, if you can do it okay.

Most damaging to the hospital was that while the jury exonerated *all* the named employees, it found the hospital derivatively liable for the conduct of unnamed employees. The jury awarded Dr. Thompson $90,000 for economic loss, mental anguish and inconvenience.

If hospitals fail to act on physicians' disruptive behavior, fearing their actions won't be upheld in court, this case shows that the trauma arising out of that failure to act can be greater. Rather than being in a strong position in court, on the basis of a clear record showing that action was based upon reasonable hospital concerns, this hospital found itself in a weak position, have to react to Dr. Thompson's characterization of events. Although she didn't allege defamation, clearly this type of situation would invite such a claim.

The medical staff and corporate bylaws must provide methods by which oral warnings, letters of reprimand and suspension of admitting privileges for a period of a week or two weeks may be used by the hospital as warnings to a disruptive physician. Such language should provide that in these instances no due process hearing is required. The effect upon the physician is not sufficient to warrant a due process hearing. And, it is unlikely that a court will enjoin a hospital from acting without a hearing or that a court will assess damages for a suspension for a term of 30 days or less. If the bylaws require due process hearings before any action can be taken the effect will be to stifle such action, for the cost and trauma will outweigh the likely effect.

If efforts to deal with the problem over a period of time prove unavailing, formal action pursuant to the bylaws should be initiated. Once again, hospital counsel should be involved throughout to assure compliance with the bylaws and to eliminate from participation in the proceedings any physician or board member who might be sufficiently biased to jeopardize the fairness of the proceedings should an adverse decision be contested in court.

If the procedure is inherently fair and in compliance with the bylaws, the hospital should have little to fear. The courts have made it abundantly clear that the need of the hospital to carry out its primary obligation of providing patient care in an atmosphere of calm, order and respect for the dignity of all need not be sacrificed to the disruptive proclivities of any appointee of the medical staff no matter how good a clinical physician he may be.

Medical Practice Question

EDITOR'S NOTE: *From time to time medical practice questions from organizations with a legitimate interest in the information are referred to the Scientific Board by the Quality Care Review Commission of the California Medical Association. The opinions offered are based on training, experience and literature reviewed by specialists. These opinions are, however, informational only and should not be interpreted as directives, instructions or policy statements.*

Physician as Assistant at Cataract Surgery

QUESTION:

If assistance is needed during the performance of cataract extraction, does the assistant need to have the training, experience and skills of a physician and surgeon? If so, what functions are performed by that assistant physician and surgeon?

OPINION:

In the opinion of the Scientific Advisory Panel on Ophthalmology, the assistance of a physician, trained in diseases and surgery of the eye, during intraoperative procedures such as cataract extraction is established medical practice. Recent advances in cataract surgery involving greater levels of technology and its attendant complexity have not diminished the need for such professional surgical assistance.

Among the considerations that place this in the patient's best interest are the following:

- The presence of a surgical assistant with the training, experience and skill of an ophthalmologist is optimal for many important steps during routine intraocular surgery, especially should emergencies occur such as hemorrhage, vitreous loss or anesthesia complications.
- Intraocular surgery is delicate and the initial procedure must be done with maximum skill and judgment. The assistant surgeon aids the surgeon to ensure the patient the best possible surgical results.
- On rare occasions, the surgical assistant may be required to complete an operation in the event the surgeon becomes disabled.

The functions carried out by an assistant at cataract extraction will vary depending on the technique used, the skill of the surgeon, the equipment required for the operation and the skill of the assistant.

—*The Western Journal of Medicine,* Sept., 1985

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Marketing Your Medical Staff

IRA H. SCHLEZINGER

Introduction

In case you haven't noticed, it's a tough world out there. The fact is:

- Patient days are down
- Length of stay is an issue vis-a-vis DRG's
- Acute care is being de-emphasized/Ambulatory Care encouraged
- Competition surrounds us, and many don't know how to compete
- Fiscal position is at risk
- Capital positioning is an issue
- Manpower resources are less available
- Technology is less affordable and in greater demand
- Public expectations are changing
- Acquisitions are the rage
- Recognizing the advantages of systems and trying to decide who to associate with is an issue
- Marketing is seen as "the" answer
- And, the stakeholders are restless
- Stakeholders are defined as those individuals, or groups of individuals who have the right to expect that their needs/values/beliefs will be supported by the institution. The failure to do so may result in the imposition of sanctions.
- Stakeholder groups include patients, trustees, insurance companies, corporate purchasers, etc.
- The preeminent stakeholder—the one that still controls or influences most of the action—is the voluntary medical staff.

Medical Staff Environment

In case you haven't noticed, hospitals aren't the only ones experiencing tough times.

- Physicians are being confronted with pressures from medical and entrepreneurial alternative delivery systems, compounded by prospective reimbursement, a new generation of practitioners entering the marketing, and by a declining use rate.
- Many are responding by developing closer associations and stronger loyalties to those hospitals they feel will best serve their individual and corporate interests, and abandoning the ones that don't.
- As we look at the medical staff as both stakeholders and as a markets, there are a number of givens.

A. Physicians currently, and will continue to, make up the single largest element of any hospital's marketing and/or customer profile. Five years ago, 75% to 80% of the admissions to a given hospital came as a direct result of physician influence; 2% to 5% came as a result of direct patient referral programs, such as hospital-controlled substance-abuse or chronic pain programs; and 20% to 22% came through emergency room admissions. The overwhelming majority of physicians with a choice had staff appointments at more than one hospital.

Today, the national profile would suggest 5% to 7% of admissions will come from medical alternative delivery systems such as HMOs and PPOs; 8% to 12% will come as a result of hospital-controlled portals of entry; and 18% to 20% will come as a result of direct hospital admissions through emergency rooms. The profile for HMO/PPO portal of entry is expected to grow at the rate of 1% per year over the next five years. It still means that from 60% to 70% come from the voluntary medical staff.

B. In discussing the concept of marketing the voluntary medical staff, one is not dealing with a homogeneous group. Marketing "primary care" physicians is markedly different than being the advocate for a "specialty group." "Solo practices" are substantially different than group or "partnership associations." New physicians are promoted in a different way than those with established practices. Physicians located in hospital-controlled facilities are markedly different than those operating from freestanding units, etc.

C. Acceptance of the marketing mandate will vary to a great extent, dependent on a given physician's age.

IRA H. SCHLEZINGER, Vice President for Planning and Marketing, Hillcrest Medical Center, Tulsa, OK.

This article is adapted from a paper presented by Mr. Ira H. Schlezinger to the Tennessee Hospital Association.

Those physicians just completing a residency and/or fellowship, normally up to 35 years of age, have been conditioned to the new competition and medical reimbursement. They know they will have to be far more creative and aggressive if they are to survive, let alone prosper. Many are angry because their perception of what their lives would be like when they entered medical school has markedly altered. At a minimum, they'll be a malleable group.

Those physicians who are 55 and over, who have been in practice for 20-30 years, who have proven their success, will not be significantly affected by the new environment in either their competitive position or the financial quality of their lives. For those in this age group who haven't made it, there is not much you or anyone else can do. In most cases, unless they have younger associates, they will not "buy in" as quickly, if at all.

At clear risk is a third category: those individuals between the ages of 35 and 55 who have been in practice 5-20 years. They have built their expectations and their practices with a mind-set that the demand and reimbursement trend were likely to continue. This is the group that, in many ways, needs the most help, and may be the most difficult to deal with. In terms of maturing practices, it is also the most important segment to the hospital.

D. Hospitals must accept the fact that they will not be immediately accepted or trusted as they move into marketing the medical staff. The concept of "trust me, I'm here to help you" is just about as believable to many physicians as the phrase, "The check is in the mail," or "I never got the message," or "Of course, I'll respect you in the morning." That lack of trust or confidence or acceptance is, in many instances, understandable. For example, hospital movement into self-referral markets has ruled out the gatekeeper, the physician; hospital acceptance of medical alternate delivery systems, like HMO/PPOs, has put pressure on physicians to be joiners as well; hospital reductions in force have made it difficult for physicians to practice in the old comfortable style; and finally, and perhaps most significantly, hospitals haven't done such a great job of marketing their own wares, let alone a new product line. The bottom line is that hospitals and physicians have traditionally had adversarial, albeit friendly, relationships, and now we must be mutually supportive in order to survive, succeed, and prosper.

E. If you're committed to medical staff marketing, you also must be committed to doing it exceptionally well. The reality of our world is that one significant "foul up" with a member of your voluntary medical staff will offset ten success stories.
- Style is critical—please and thank-you-care and feeding are a must.
- Don't be afraid to go outside when you're in over your head. Have technocrats you can use and you can trust available.
- Don't be afraid to say no if a given task is not doable.

F. Elements of a marketing strategy for physicians is not dissimilar from general marketing in the hospital. Five major components seem to logically evolve. Specifically, hospitals need to be prepared to engage in:
- Marketing Research
- Developmental Activities
- Sales
- Advertising/Promotion
- Market Maintenance.

For this presentation, here are some specific examples of things you can, and perhaps should, be doing.

Research Component

A. Site Surveys

Most hospitals are involved in attempting to secure stronger physician association; and practice location often becomes a pivotal issue.

Start-up Practices: If a hospital has recruited, or is assisting physicians moving into the community, it is important to be prepared to give a reasonably sophisticated analysis of the demography of the area they want to practice in. Issues to be acknowledged include age, sex, income, education, location of other practitioners in the area, geographic barriers that affect traffic flow, and some observations about the economic/social culture of the area. Such research will provide strong indications as to whether there can and will be a match between a given physician and given neighborhood or community. For example, you simply would not want to introduce a foreign medical graduate, or a very young physician, into an area that is traditionally conservative, elderly, or whatever. You would not want to introduce a sub-specialist into an area that has a clear demand for primary care.

Going beyond basic demographics is also important. Locating a physician in an area that has limited visibility, inadequate parking, or may be going through transition, regardless of how attractive the acquisition price or rent may be, is short sighted. Putting a physician in a location where he or she may be in direct competition with another physician practicing at your hospital, or in a location where that individual may be in direct competition with a very successful physician, makes little or no sense in this competitive environment.

Unfortunately, many, if not most, physicians are neither able nor inclined to go through the site survey exercise for themselves. The normal doctors' questions about site include how much is the rent, how long is the lease, how many others like me are in the building, what color will the carpet be, and can I get in by July first.

Second office surveys: Established physicians must be comparably supported. Market research is important for established physicians or groups that are looking to establish a presence outside of their current service area.

They see opportunities in rural areas, or suburban growth areas. They start out with a marketing mind set. Helping such physicians determine geographic areas with true potential, the demographics of the area, the current referral patterns, the names and ages of the actors who currently have achieved penetration, and levels of satisfaction with the services being provided is all useful information. Again, the time and talent to do this independently is often lacking. Here is a good opportunity for the hospital to score some points with established physicians, and perhaps at the same time, achieve a geographic dispersion strategy.

B. Product Development

With increasing frequency, physicians are looking for “hooks” that will make their practices unique, or at least distinctive.

On the distinctive side, I've heard of physicians that have located their offices in old buildings, decorated with antiques, and gotten on the historical registry. A physician in Tulsa makes house calls in an old physician's horse-drawn wagon.

At the other end of the spectrum, physicians have established computer connections between their offices and patients. Patients are able to communicate blood pressure/weight/and other factors for a “running” medical record and are able to extract the latest consumer health information.

On the unique side, physicians are looking for program advantages. With increasing frequency, physicians are looking to be positioned as the “behavioral medicine,” “metabolic disease,” “house call,” “sports medicine” physician in a given geographic area. Research as to demand for these types of physicians, and if demand exists, how to position them accordingly is critical. Hospitals are generally able to do this kind of research.

C. Public Opinion Surveys

Hospitals traditionally have done market research about perceptions of past patients, public opinion surveys about the hospital, surveys about business and industry needs, employee climate surveys and medical staff expectation surveys. Seldom, however, do we pursue research into the public's perception of a given hospital's voluntary medical staff. Such issues as name recognition, perceived hospital association, satisfaction with style and quality of a practice can all be secured with good market research. In addition, such surveys could determine what the public wants of a private physician. Focus groups, mail surveys, and telephone polls are all effective techniques. Such research provides both the hospital and the practitioner direction about areas needing attention, while at the same time not threatening any one physician.

Development Component

Marketing for physicians during their first three to five years:

A. Practice Development Assistance

Best start with a premise that most physicians are trained to be doctors, not business men. Hands-on advice and direction provided by someone on your staff with experience (a medical staff liaison and/or development officer), or through a contractual relationship is, in today's environment, essential. A thousand issues such as helping physicians set up the office, recruiting support personnel, pricing, initial promotion, hours to be open, patient relations, securing referrals are more than just common sense issues. There is clearly a right and wrong way of doing those things, and one does not need to learn from experience. It should also be noted that the care and feeding of a practice is just as critical at the 90-, 180-, 360-day mark as it is from day one. Most hospitals do a good job of making a new physician feel welcome. We send flowers, take them to dinner, encourage a few referrals. We also tend to ignore them once they become a familiar face. Having a practice development service available, making sure of the level of competence, and a commiting to discretion are all musts.

B. Creative Financial Support

Although hospitals are clearly in the driver's seat with increased availability of physicians, we still need to recruit a few good men and women. Having a formal physician recruitment and retention program is a good marketing technique. Specific elements might include subsidizing the cost of initial recruiting, rent deferment or forgiveness, income guarantees, and low interest loans. Such efforts should be directed to not only new physicians, but those being recruited into established practices. R/R programs are a simple way to prove how much you view the physician customer as an essential element in your marketing strategy. A word of caution, however. Once you start the process of financial support, make sure you maintain it on a solid business footing. Don't overextend a practitioner with your generosity, just as they appreciate your support in the beginning, they resent over aggressive attempts at financial recovery, especially when things are not progressing well in their practices. More than one physician has been bankrupted by a hospital whose single motive was trying to help.

C. Physician Referral Services

More and more hospitals are developing and promoting physician referral services. This is simply the promotion of a visible access number staffed by a reasonably competent professional who can determine what type of a physician a caller might be needing. Once that determination is made, two or three names, their practice locations, and telephone numbers are given to a caller. The caller then makes the contact. No attempt is made to do financial screening, or follow up with the caller. The physician referral service is generally a brokerage activity. Promotion and follow-up of the physician referral service is just as important as the service itself. Using yellow pages, paid or public electronic and/or print media, billboards, bumper stickers, are all effective marketing techniques. It is also important to notify the physicians that requests have been received and forwarded to their office. Finally, it's useful to monitor services in terms of how callers find the number. It enables you to better invest your promotional dollars.

D. Network Opportunities

Recognizing that new physicians are simply not going to be busy from day one, the development of networks within which a physician can be "positioned" for a period of time is desirable. Networks fall into several categories, including urgent care networks, primary care networks, and industrial/occupational medicine services networks. Generally, networks are either owned, operated, or joint ventured by the hospital and, as a service entity, can provide temporary homes for new physicians or fall back positions for physicians going through tough times.

Promotion Component

There is a tremendous amount of pressure out there to market, primarily with advertising and promotion techniques. Such efforts are seen as the fastest and least painful ways of gaining market position. Just as one should not overreact to such pressures, one should not ignore them as a marketing technique for one's medical staff.

General Imaging Campaigns: The public positioning of the voluntary medical staff is important. Communicating to and convincing the consuming public that one's physicians are younger, more sensitive, more available, better educated, better priced, and better looking than that of the competition establishes a receptive mind set. Medical staff sponsorship of public educational events, providing health fairs, health promotion hints, public screening activities and supporting community drive efforts are all techniques the hospitals can pursue on behalf of their physicians.

Individual Showcasing: In many situations, it's possible to bring visibility to a given physician and his/her practice. This should involve both new and established physicians. Developing a system of recognitions such as awards, features in magazines and publications, selection to introduce a town hall series, a speakers' bureau participant, talk shows, issue specific speakers, are all examples of individual showcasing.

Direct Mail Campaigns: In situations where a physician has a clearly defined service area, direct mail campaigns are useful marketing techniques to keep his/her name before the public. Announcements of new practices; revised office hours; a senior citizens' discount program; the introduction of a new test or vaccine; a new associate; good health classes, are all established vehicles to establish or re-establish name recognition and obtain business. The development of a basic approach or prototype that can be used with and for non-competitive practices helps avoid reinvention of the "mail campaign" wheel. All of this can be coordinated by a hospital's PR and/or marketing department.

Selling the Medical Staff

It's sometimes difficult to differentiate between advertising and promoting the medical staff and the actual selling of their services. In most instances, you will be or selling hospital services that you control, of which the physician is a critical actor. Examples include:

- HMO/PPOs—where you're selling enrollment opportunities
- Urgent Care Centers—where you're selling an episodic service
- Industrial Medicine/Occupational Health—where you're selling contractual relationships
- Wellness/Promotion programs—where you're selling memberships

All of these efforts, if successful, will result in either a contract, fee for service, or percentage arrangement with participants.

Part of the sales technique will clearly tie back to the availability and acceptability of not only the concept, but the physician actually providing the service. Choosing and promoting physicians accordingly is critical.

Market Maintenance

Once a practice is established, it's a tactical mistake to believe that it can and will sustain itself without continued attention from someone other than the physician. In these situations, the marketing initiatives should be directed toward assisting the physician either maintain financial strength, stay current on practice techniques, and/or develop creative ways to begin winding down a practice. Examples of hospital-sponsored initiatives in each of these are of note.

A. Joint Venturing

Acquisition of buildings and/or equipment that further ties a physician and a hospital together is a desirable objective. Ventures where both buy in—where the physician gets a tax break and capital backing, and the hospital is assured of continued support, are being pursued in such areas as physicians' buildings, radiology equipment, aerobics facilities, nursing homes.

B. Group Purchasing

Physicians are generally appreciative when systems are in place that allow them to get price discounts. Such items as paper, reproduction equipment, computers, telephones, office supplies have all been successful targets for joint purchase initiatives.

C. Office-Practice Management

Opportunities include:

1. Educational Programs
    - Practice Management
    - Technical Services
2. Actual Practice Management Consulting Services

D. Phase-Out Assistance

There comes a time in every practitioner's life when he wants to sit back and smell the roses. He or she also would like his or her patients protected, perhaps some return on their years of investment, a smooth transition, and perhaps a less demanding role for themselves. The hospital obviously wants to keep the patients flowing in. "Phase-out" programs that enable practices to be combined, new physicians to be recruited, existing physicians to wind down slowly are all desirable. Such efforts also need to be handled with kid gloves lest feelings be hurt. A support strategy that enables a hospital to move quickly in situations where a physician passes away, or disappears is also essential. A formally designated medical staff liaison person is especially important in these situations.

E. Selling a Practice

Providing assistance in appraising relative worth of a practice, identifying potential purchasers, financially supporting the purchaser, or assisting in negotiating a role for the selling physician if he/she chooses to maintain some practice involvement, are all part of the practice sale scenario. I'm convinced you will see more attempts to sell practices, and greater receptivity to buying established practices in the years ahead.

F. Practice Mergers

Another phenomenon of the current competitive environment is the merger of practices. These seem to fall into three groupings of activities:

- Establishing a primary practice presence in two locations
- Merger of sub-specialty disciplines such as neurology, neurosurgery, psychiatry
- Bringing together primary care practices and multi-specialty groups

All efforts can use the services of a good "broker"—a role hospitals can provide directly or through contractual arrangements.

Conclusion

The bottom line in all of this is that hospitals simply can't afford not to have a marketing strategy for its medical staff. The options as to approach are as varied as a Chinese menu. There are, however, some critial elements in pursuit of any programs.

1. Involve your medical staff in selecting appropriate tactics. Don't assume you know what they need.
2. Select appropriate individuals to make it happen . . . those with impeccable personal and professional skills.
3. Commit the necessary resources to make it happen in a timely manner.
4. Prepare yourself to maintain the effort indefinitely.
5. Develop a system of communications and report back to keep your physician customers informed of successes.
6. Be prepared for the occasional "flack" from those who do not see the need or feel that they are not being treated fairly.

Failure to pursue to medical staff marketing mandate, as hard and arduous as it may be, is clearly a tactical error.

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Tocainide

JAMES J. HANYOK, PHARM. D.

Introduction

Tocainide (Tonocard®) is a new antiarrhythmic agent similar to lidocaine in structure and pharmacologic properties. Unlike lidocaine, tocainide possesses good oral bioavailability and a long elimination half-life, thus allowing convenient, long-term oral therapy. Tocainide is effective in the treatment of ventricular arrhythmias associated with a variety of cardiac disorders and may prove to be a useful alternative to conventional agents.

Pharmacology and Pharmacokinetics

Tocainide has electrophysiologic properties similar to lidocaine and is classified as a Type I-B antiarrhythmic agent.[1] In isolated canine Purkinje fibers, tocainide depresses membrane responsiveness and shortens both the effective refractory period and action potential duration, but increases the effective refractory period/action potential ratio.[2] Clinical electrophysiologic studies in patients with cardiac disease have shown tocainide to produce only minor electrophysiologic changes at serum concentrations effective against ventricular arrhythmias.[3,4] Sinus node function and atrial, AV nodal, and ventricular conduction are not significantly affected,[3,4] but small decreases in atrial, AV nodal, and ventricular effective refractory periods may result.[3] Tocainide produces no electrocardiographic changes, except a slight decrease in the QTc interval in some patients.[3]

In patients with compensated left ventricular dysfunction, intravenous administration of tocainide results in small increases in vascular resistance, arterial pressure, and left ventricular end-diastolic pressure.[5] During chronic oral therapy, tocainide is well tolerated hemodynamically in patients with congestive heart failure.[6]

Tocainide is rapidly absorbed following oral administration, with peak plasma concentrations occurring at 0.5 to 2.0 hours.[7,8] Bioavailability approaches 100%.[7,8] The presence of food decreases the rate but not the extent of absorption.[8] The volume of distribution of tocainide ranges from 1.5 to 3.0 l/kg, and approximately 50% of the drug is bound to plasma proteins.[7,8] About 40% of a dose is excreted unchanged in the urine, though alkalinization of the urine can decrease this fraction by up to 75%.[8] Tocainide is metabolized in the liver principally by carboxylation and formation of a glucuronide conjugate; its metabolites are pharmacologically inactive. The terminal elimination half-life of tocainide averages 11 to 14 hours in healthy subjects and patients with acute myocardial infarction (MI).[7,8] The elimination half-life is increased in patients with impaired renal function due to decreased clearance.[9] Usual oral doses of tocainide result in plasma concentrations ranging from 6 to 12 ug/ml.[6] Plasma concentrations are not likely to be useful in predicting the response to tocainide therapy, since clinical trials have shown no difference between plasma concentrations in responders and nonresponders.[6,10] However, the occurrence of adverse effects with tocainide may be associated with increased plasma concentrations.[10]

Clinical Studies

Tocainide has been evaluated in the treatment of ventricular arrhythmias associated with acute MI[11-13] and in the treatment of chronic ventricular arrhythmias.[6,10,14-16]

Tocainide has been shown to be effective in reducing the frequency of ventricular premature depolarizations (VPD's) and complex ventricular arrhythmias in patients with acute MI,[11,12] though one study found no difference between tocainide and placebo in the incidence of VPD's, paired VPD's, and ventricular tachycardia (VT) episodes during a 24-hour period in acute MI.[11] Tocainide appears to be ineffective in preventing ventricular fibrillation (VF) and symptomatic VT in the first 24 to 48 hours post-MI.[12,13]

For the treatment of chronic ventricular arrhythmias, including symptomatic VT and VF, tocainide is effective in approximately 50 to 60% of patients.[6,10,14-16] In most studies, antiarrhythmic therapy with quinidine, procainamide and disopyramide had been unsuccessful prior to the use of tocainide. Podrid and Lown[10] found to-

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JAMES J. HANYOK, PHARM. D., Post-doctorate Pharmacy Fellow, Hartford Hospital, Hartford, CT., Assistant Clinical Professor, University of Connecticut, School of Pharmacy, Storrs, CT.

This new series on Drug Information Updates from the Hartford Hospital are supplied by Charles H. Nightingale, PH.D., Director of Pharmacy Services, Hartford Hospital.

Editors: Moses Sing Sum Chow, PHARM. D. and Robert A. Quercia, M.S., R.PH.

cainide to be effective in 55 of 120 patients (46%) with symptomatic VT or VF, including 9 of 20 patients in whom electrophysiologic testing was performed. Though short-term suppression of ventricular arrhythmias with tocainide is achieved in many cases, some investigators have found its usefulness during chronic therapy to be limited.[10, 15]

The antiarrhythmic response to lidocaine may be predictive of the response to tocainide therapy.[6, 10] Winkle, et al[6] reported that 63% of patients responding to lidocaine had their arrhythmias suppressed with tocainide, whereas a positive response to tocainide occurred in only 17% of patients in whom lidocaine was ineffective.

Adverse Effects

Adverse effects are common with tocainide, most frequently involving the CNS and GI tract. However, in many cases these are mild, transient, and reversible following dose reduction or administration with food.[6] Discontinuation of tocainide because of side effects is necessary in approximately 11% of patients,[16] though less favorable results have been reported.[10, 15] CNS adverse effects include lightheadedness, tremor, ataxia, dizziness, nightmares, confusion and slurred speech. Gastrointestinal reactions include nausea, vomiting, and anorexia. Other adverse effects include rash, fever, worsening of CHF, and aggravation of arrhythmias.

Dosing

The usual initial adult dose of tocainide for the treatment of ventricular arrhythmias is 400 mg every 8 hours. The usual adult maintenance dose is 1200 to 1800 mg/day, administered in divided doses every 8 hours. Doses up to 2400 mg daily have been used, but doses greater than 2400 mg are not recommended because of intolerable side effects. Dose reduction may be necessary in patients with impaired renal function or hepatic disease.

Cost

	Average Wholesale Price/100 tablets
400 mg tablets	$42.01
600 mg tablets	$53.56

Conclusion

Tocainide is a new lidocaine-like antiarrhythmic agent with activity after oral administration. It is effective in the treatment of chronic ventricular arrhythmias, including those refractory to other drugs, in about 60% of patients. It may be particularly effective in patients responsive to lidocaine. Tocainide is well-tolerated in most cases, but may cause CNS and GI side effects which limit its use in long-term therapy.

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Influenza Prevention for 1985-1986

THE MEDICAL LETTER

A trivalent inactivated influenza vaccine is now available for the 1985-1986 influenza season (Morbid Mortal Weekly Rep, 34:261, May 17, 1985). This year's vaccine contains the same antigens used in last year's vaccine: A/Philippines/2/82 (H3N2), A/Chile/1/83 (H1N1), and B/USSR/100/83. Even though the two vaccines are identical, last year's products cannot be used because they have a June 30, 1985 expiration date, and patients vaccinated last year need revaccination because the protective effect declines over the course of a year. The 1985-1986 vaccine is available in the USA in a split-virus (subvirion) or whole-virus preparation from Squibb-Connaught *(Fluzone),* and as a split-virus preparation from Parke-Davis *(Fluogen)* or Wyeth. In Canada the vaccine is available from Connaught, and whole-virus vaccine is also available from Institut Armand-Frappier *(Fluviral).*

Indications

Vaccination against influenza is recommended especially for adults and children with chronic pulmonary, cardiovascular, or renal disease, diabetes mellitus, chronic severe anemia (such as sickle cell disease), or immunological impairment, for residents of nursing homes and other chronic-care facilities, and for everyone more than 65 years old. It is also recommended for medical personnel to protect themselves and their high-risk patients. The vaccine should be given in October or November; if given earlier, protection may wane by spring, when outbreaks frequently occur.

Adverse Effects

Influenza vaccine can cause local redness and induration at the injection site for a day or two in some patients. Less often, fever, chills, myalgia, and malaise may occur, beginning six to 12 hours after vaccination and lasting one to two days; such effects were more frequent in children given whole-virus vaccine (PF Wright et al, Rev Infect Dis, 5:758, 1983), and sometimes were accompanied by febrile convulsions. Hypersensitivity reactions are rare, but the vaccine should not be given to patients who have previously had serious allergic reactions to eggs or egg products.

Interactions

Influenza vaccine has been reported to decrease hepatic metabolism and increase serum concentrations of theophylline and to increase the effects of phenytoin and oral anticoagulants. Other studies, however, have been unable to confirm these findings *(Medical Letter Handbook of Adverse Drug Interactions,* 1985, p 46; IH Gomolin et al, J Am Geriatr Soc, 33:269, April, 1985; PA Winstanley et al, Br J Clin Pharmacol, 20:47, July 1985).

Dosage and Administration

A single intramuscular 0.5 ml dose of either split-virus or whole-virus vaccine is recommended for adults and children more than 12 years old. Children less than 13 years old should receive only the split-virus vaccine; the dose is 0.25 ml for children six to 35 months old and 0.5 ml for those three to 12 years old. High-risk children less than 13 years old who did not receive at least one dose of the vaccines available from 1978-79 to 1984-85 should receive two doses of this year's vaccine, a minimum of four weeks apart. The US Public Health Service recommends that pregnant women for whom influenza vaccine is otherwise indicated should be vaccinated during the second or third trimester. Influenza vaccine can be given at the same time as pneumococcal vaccine (at a different site) with no decrease in effectiveness or increase in toxicity of either; pneumococcal vaccine is given only once.

Effectiveness

Recent reports suggest that influenza vaccine is less effective in nursing home residents than in younger age groups (Morbid Mortal Weekly Rep, 34:478, Aug 9, 1985; PA Patriarca et al, JAMA, 253:1136, 1985), possibly due to an age-related decline in immune response and repeated exposure in a closed, crowded environment. However, even when the vaccine does not prevent influenza infection, it may decrease the severity of illness.

Amantadine

Oral amantadine (*Symmetrel*—DuPont), 200 mg once daily or 100 mg twice daily, starting before exposure to influenza A and continuing throughout the period of exposure (for up to 90 days), can prevent illness in 70% to 90% of healthy adults. Patients more than 65 years old should take 100 mg once daily. Dosage should be decrased for patients with renal impairment (Morbid Mortal Weekly Rep, 34:261, May 17, 1985; FY Aoki and DS Sitar, Clin Pharmacol Ther, 37:137, 1985). Previous vaccination enhances the effectiveness of the drug, and amantadine apparently does not interfere with the effectiveness of the vaccine. Amantadine does not prevent infection with influenza B strains. The results of some controlled trials indicate that amantadine, begun within 24 to 48 hours after symptoms have appeared, may decrease the duration of illness in influenza A infections (JW Little et al, Ann Intern Med, 85:177, 1976; LP Van Voris et al, JAMA, 245:1128, 1981; SW Younkin et al, Antimicrob Agents Chemother, 23:577, 1983). Whether prophylaxis or treatment with amantadine can prevent influenza-related deaths in high-risk patients is not known.

Insomnia, lightheadedness, nervousness, difficulty in concentrating, and drowsiness occur occasionally in patients taking amantadine; symptoms generally appear in the first 48 hours of treatment and may subside even when the drug is continued. These neurological reactions may be more troublesome for elderly patients.

Conclusion

Trivalent influenza vaccine for the 1985-1986 season is recommended especially for high-risk patients and medical personnel who may come in contact with such patients. Daily prophylaxis with amantadine can prevent influenza A infection, and early treatment with the drug may decrease the duration of illness.

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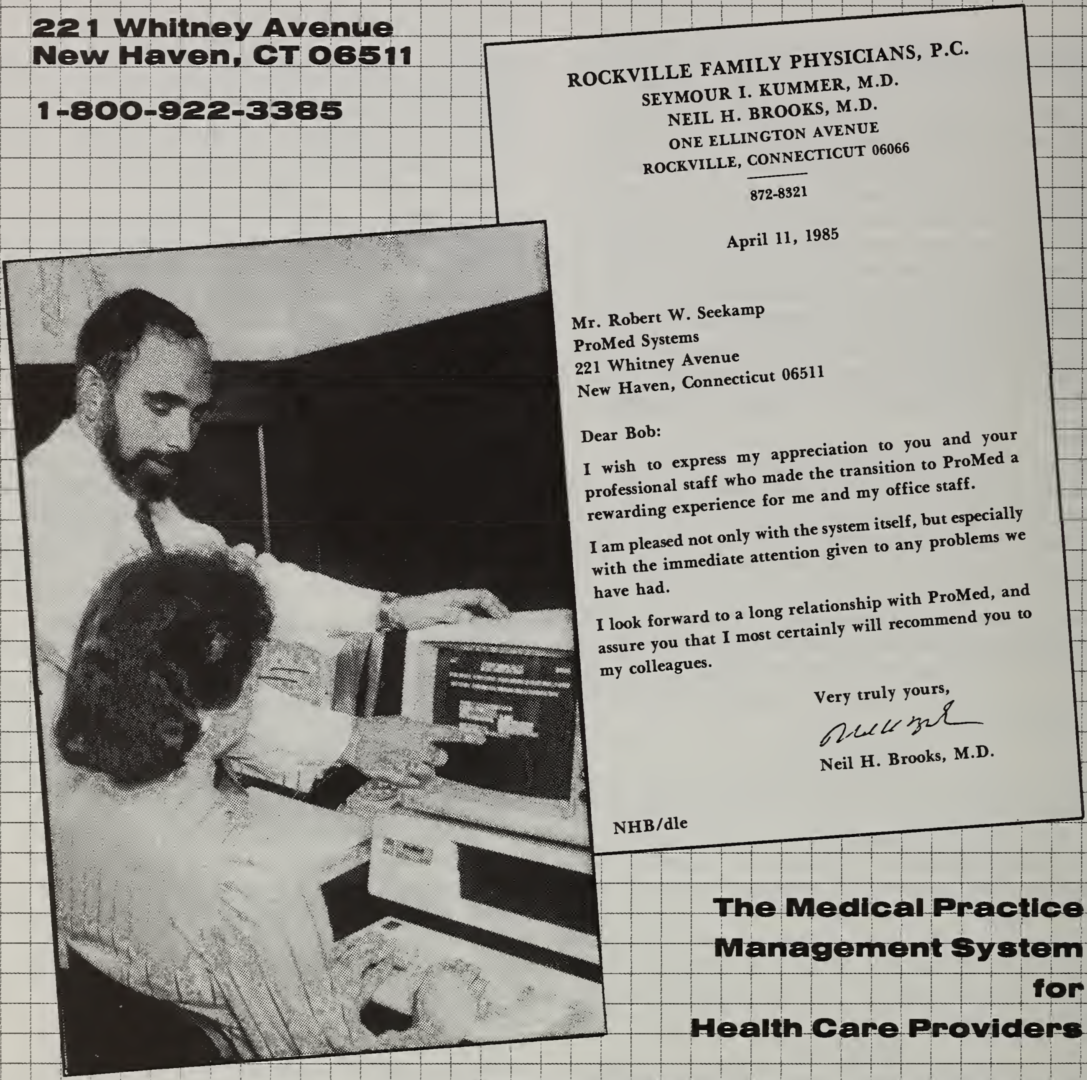

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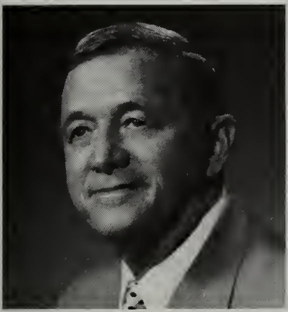

While visiting the County Associations over the past two months, the two most pressing issues which surfaced were the concern over the present professional liability crisis and also the proliferation and penetration of the multiple Alternative Health Care Delivery Systems on the Connecticut scene. The professional liability problem is being aggressively addressed by the Society, and strategies are being organized on a daily basis. The question arises, however, as to what role (if any) the Connecticut State Medical Society should play in dealing with the impact of the increasing number of Health Care Delivery Systems on our membership. Presently, in the State of Connecticut there are approximately thirteen HMO's which are operating at different levels of development and success. The U.S. Health Care Systems, Inc., the largest and most aggressive IPA-HMO in the United States has formally filed to operate in Connecticut. This will be the first national for-profit HMO in Connecticut. Recently, two Hospital-PPO networks have been established and will soon commence marketing activities. Finally, Medicare and Medicaid may soon enter into a capitation system of reimbursement.

Presented with a similar set of circumstances, the Georgia Medical Society has taken a bold step by establishing its own statewide IPA-HMO. After eighteen months of planning, the program will become operational on January 1, 1986. There are five thousand practicing physicians in the State of Georgia. Approximately two-thousand-one-hundred-fifty physicians have joined the IPA-HMO, and it is hopeful that four-thousand will eventually participate. As you might expect, the project has taken an extensive amount of "time, talent, and treasure" of many dedicated Georgian physicians. Georgian hospitals and business groups are interested in the operation. It is expected that the momentum of the project will potentially result in increased State Society membership. Anti-trust problems will be avoided as long as non-exclusive contracts with physician participants are enacted.

When the Georgia House of Delegates originally debated the issue, several options were considered: 1) No change-maintain the status quo 2) Improve the advisory function of the Society 3) Promote physician directed utilization review for Health Care Delivery Systems 4) Formation of a PPO 5) Formation of an IPA 6) Formation of an IPO-HMO 7) Opposition to all Alternative Health Plans.

The evaluation of advantages and disadvantages of each of the options involved the following criteria: 1) Level of anti-trust risk 2) Level of financial risk 3) Expenditure of resources 4) Degree of impact on health care services market 5) Degree of impact on health care financing market 6) Implementation time.

The proposition of a Connecticut State Medical Society Statewide sponsored IPA-HMO was discussed at length at the recent October Council Meeting. The matter is being referred to the House of Delegates. The feasibility and credibility of the proposal will be debated by the House of Delegates on November 20, 1985. If the House chooses to move forward on this ambitious enterprise, an Ad-Hoc Steering Committee will be appointed to draw up a Business Plan and report back to the House as soon as possible for further action.

The decision to form our Connecticut Medical Insurance Company involved inherent risks but was a courageous timely demonstration of leadership by the Connecticut State Medical Society. Once again, a challenge has emerged. If the Connecticut State Medical Society can establish its own Professional Liability Insurance Company, why can't we establish our own Health Insurance Company? Failure of the Society to exert leadership and direction at this time would be an abrogation of responsibility.

Let us realistically scrutinize the issues and "Go For It!" if the opportunity is viable.

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Reflections on Medicine

Brain Receptors

ROBERT U. MASSEY, M.D.

Surely others have made this observation and found it too obvious to mention, but I have often noticed that a word, new to me, a name, or a concept, will recur several times in fairly rapid succession after a first encounter. I should have said first *recalled* encounter, for I suspect that many, maybe most, bits of new information get past us without ever stopping. There is, I am sure, a good explanation for this in someone's learning theory; neurotransmitters are undoubtedly at work, and my mechanistic way of thinking leads me to imagine receptors forming ready to latch onto the new idea or name whenever it comes around again.

Last spring at the meeting of the Association for the History of Medicine, I heard a paper presented by Dr. William DeVries on the history of open heart surgery and the development of the artificial heart. He told about Ferdinand Sauerbruch of Berlin, whose airtight chamber with its partial vacuum enclosing both surgeon and patient's body allowed the chest to be entered without a fatal pneumothorax. His slides showing the 1904 photographs of the small, airtight, wooden room, the anesthetist sitting outside by the patient's head, Sauerbruch and probably von Mikulicz inside working over an open chest, must have made an impression strong enough to develop some Sauerbruch receptors in my brain.

Later in the summer, while we were visiting the medical school at Hannover, a faculty member showed me a newly published book which contained the minutes of *Die Mittwoch-Gesellschaft,* the Wednesday Society.[1] These minutes, which spanned the 12 years from the beginning of the Third Reich to Wednesday, 26 July, 1944, six days following the attempt on Hitler's life, had been recently uncovered by Klaus Scholder at the University of Tübingen during the course of his work on the history of the church during that dark period. The membership of this small society, an old intellectual club founded in Berlin in 1863, had been limited to 16 men. I scanned the names; the list included the physicist, Werner Heisenberg, and the German Chief of Staff, General Ludwig Beck; Ferdinand Sauerbruch, Chief Surgeon at the Charité, was a member from 1933 to 1944. During these years the club appeared to turn from its apolitical scientific and philosophic interests to assuming a connection with the resistance. According to Sauerbruch in his autobiography,[2] nine members were executed after 20 July 1944; Scholder confirms that no fewer than four were directly involved in the bomb plot.

My third encounter with Sauerbruch came in a recently published book, *Famous Operations,*[3] in which the author, Harold Ellis, surgeon at Westminster Hospital, London, tells the story of the 1928 illness of King George V. Following a right lower lobe pneumonia, the 64-year-old monarch had developed an empyema which was drained by rib resection. Although the King's health improved, a residual abscess remained which, after almost seven months, required further surgery, successfully performed by Wilfred Trotter and Sir Hugh Rigby. "There is no truth at all in the rumor, which persists to this day," wrote Ellis, "that Professor Ferdinand Sauerbruch was secretly summoned to London to put things right." Sauerbruch himself, in his autobiography, called the whole thing "a canard of the first magnitude." A German newspaper article reported that he had received 1,000,000 gold marks and a Rolls Royce as a fee for his alleged surgery. Sauerbruch does admit that he was asked for his opinion after being sent the X-ray films. "As it happened," he wrote, "my opinion agreed altogether with that of the English surgeons."

After the War and 17 years after the King's empyema, Sauerbruch was summoned before a de-nazification court because he had accepted the title of *Staatsrat.* The tribunal asked: "And where, Herr Geheimrat, have you hidden the million marks paid you by the King of England for his operation."

Sauerbruch's low pressure chamber gave way in 1909 to the more manageable intratracheal insufflation anesthesia, but he continued a vigorous career in general and thoracic surgery for more than 40 years. He is mentioned in Julius Comroe's book, *Exploring the Heart,*[4] as "Germany's great (and authoritarian) surgeon" who was in part responsible for the delay in the recognition of Werner Forssmann's accomplishment of cardiac catheterization in 1929. But that's another story, maybe requiring another set of receptors.

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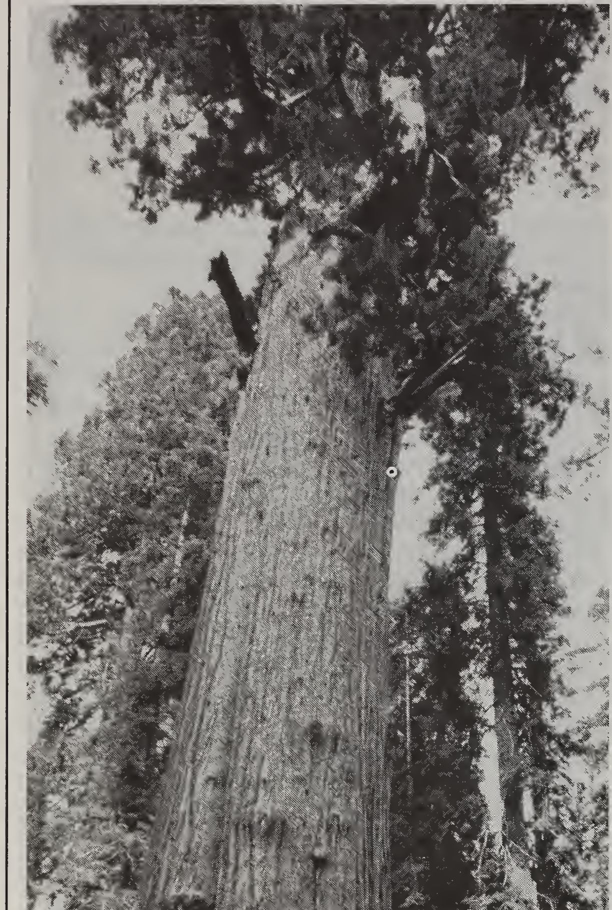
ROBERT U. MASSEY, M.D., Professor and Head, Division of Health Care Administration, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.



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Editorial

Health Care Marketing: Good Medicine or Bad?

It is probably safe to say that most physicians in Connecticut today don't give the subject of health care marketing a great deal of thought. It is also probably safe to say that of those who do, most still feel rather uneasy, if not downright hostile, toward the idea, especially in terms of how it relates to their concept of the practice of medicine.

Most physicians would concede, of course, that there are certainly aspects of being a doctor that are "businesslike." Most also would concede that medical care, as a service, certainly shares similarities with other "goods and services" offered in our economy. But saying that is hardly the same as saying, as some marketeers appear to do, that being a doctor is really not that much different from being the head of any other small business.

As physicians see it, such a claim totally ignores the principles that undergird the practice of medicine. These principles implore a doctor to serve, to help heal, to care. They do not encourage physicians to tell the world how wonderful they are or instruct them on how to steal patients from their colleagues.

But is such self promotion and shrewd scheming really what marketing is all about? While some of the more notorious stories one hears about marketing in a health care setting might lead one to think so (i.e., lotteries to encourage weekend hospital admissions), the truth is most such stories involve institutions and providers who really have no idea of what true health care marketing is all about. For rather than being glitz and gimmicks, hype and hoopla, true health care marketing is really a philosophy that stresses that the key to any business success lies not in focusing on the needs of the business itself, but rather on those of the consumer, on whom the business depends for its existence.

Indeed, it is only to the extent that a company's products or services meet the needs of the consumer that the company can hope to enjoy any success at all.

How does one distinguish between marketing properly practiced and the myriad of sales and promotional activities often confused with this term? Perhaps the best way is by recognizing that true marketing is always outward-, rather than inward-directed.

True marketing does not begin with the question: "How can I lure more people into my office?" Rather, it begins with the query: "What is it that people want from their health care system and how can I best provide it?"

Viewed in this light, health care marketing is really not all that different from an approach that first seeks to discover what is wrong with a patient and then seeks to find a way to remedy the problem. Perhaps that is why so many physicians, upon learning what health care marketing is, conclude it is not really that different from what they have been practicing all their careers—they simply never called it "marketing" before.

One reason why marketing has received so much attention in health care circles lately is because health care itself has become so much more competitive. This is due, in part, to this nation's growing physician surplus, as well as to the efforts of government, business and insurers—the principal payors of care—all of whom see competition as yet another weapon to be used in the battle against increasing health care costs.

Since competition and marketing go, quite naturally, hand-in-hand, does that mean physicians who practice medicine from a marketing perspective must, of necessity, come to regard their colleagues and other providers, such as hospitals, with hostility and suspicion? Not necessarily, for while it is true that competition may drive providers apart in some instances, it also creates opportunities for joint ventures and other activities that could prove to be mutually beneficial as well. This is precisely the point of Ira H. Schleszinger's article, "Marketing Your Medical Staff," contained in this issue.

Like it or not, marketing is a reality in health care today and it is likely to remain so for the forseeable future. While some physicians may choose to fight it and others to ignore it, in the final analysis, it will be those who choose to understand what marketing is and to master its precepts for the betterment of patient care who will do best in the days ahead.

Albert F. May, Jr.,

Associate vice president,
public affairs,
The Connecticut Hospital Association.

Mr. May has provided advice on health care marketing matters to CHA members and has helped organize several seminars on this topic for hospital and other health care personnel.

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Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

MAGNETIC RESONANCE IMAGING (MRI): HEGEL REVISITED

To the Editor: In the August issue of *Connecticut Medicine,* there appeared an interesting article co-authored by Doctors Melville Roberts and Joseph Sadowski and entitled "The MRI Scanner and What We Don't Learn from History." Since the article made some lengthy comments and criticism of the Capital Area Health Consortium which I presently Chair, I thought it might be helpful, not to say just, to offer some basic reasons as to why some of those criticisms seem to be lacking factual foundation or credibility.

On the other hand it would be good, possibly even urbane, to begin by listing those many points on which the Consortium trustees are in agreement with the authors.

For example, they say that MRI is a marvelous diagnostic tool. Agreed. They say that there is good historical evidence that we should have an MRI in any hospital which has a major neurosurgical service. Agreed, but with this distinction: what about the services other than neurosurgical who now use MRI technology with benefit and whose utilization rate will inevitably increase as the technology is perfected? One will pardon the Capital Area Health Consortium's Chairman if he does not immediately invest his neurosurgeon friends with the mantle of supremacy of need.

They say that "the obstructionistic tactics of various cost control groups" in the 1970's was largely responsible for the retarded rate of introduction of Computerized Tomography (CT) scanner technology in Connecticut. Right on—agreed! But what is not said is that the same history of the CT foul-up which eventually put Connecticut in a 43rd position in the country for far too long is *not* going to be inevitably repeated by reason of the current strategy of the 14 hospitals in greater Hartford which the Consortium serves.

They also say that a "consolidated task force of radiologists and laymen" is now working on phase two of an allocation plan for MRI scanners and that this group has already concluded that there should be only two scanners in the state and these should be placed at Yale-New Haven Hospital and John Dempsey Hospital. The reporting is correct and the Consortium fully agrees with the authors that this group's (Statewide Health Coordinating Council) reasoning is bankrupt. That is all the more true when one realizes that this recommendation was made to the Commission on Hospitals and Health Care (CHHC) without even an attempt at a documented needs analysis, a rudimentary tool for justifying a new and costly technology.

Now to the fun part. The authors nominate the Consortium as a "self-appointed group struggling with the question of MRI." That's news to me. The Board of Trustees of the Consortium is composed of the Chief Executive Officers, the Board members (primarily Chairmen) and representative physicians from the 14 member institutions in greater Hartford, including 9 persons from the three institutions in which the authors teach and practice. All these persons seem to be, in the common parlance, the bosses of the authors. In the Consortium, it is the Board, not committees, that make all final judgments. It would be an interesting phenomenon if the authors really mean to say that the leadership of their own institutions are a "struggling group of self-appointed people."

The authors then tell us that they mined their basic information from the May 1985 Newsletter of the Capital Area Health Consortium. Fair enough. But, from here on the rigorous Hegelian logical method collapses. None of the 9 members of the MRI Committee of the Consortium is a neurosurgeon, neurologist or a radiologist, say the authors. True. But it is also true that a subcommittee of this group is chock full of these worthy types and, in fact, is co-chaired by two very fine radiologists who practice daily in the two hospitals where our authors serve with great distinction. They have offered clear and compelling evidence to the MRI committee of the clinical uses of *all* pertinent services, obviously and primarily including neurosurgery and neurology. That information, it seems to me, would have been readily available to the authors by either taking the time to write or call the Consortium (we have no indication that this ever happened), or at the very least asking a few probing questions of their in-house colleagues over the usual midmorning coffee.

Next the authors have the MRI Committee approving "a policy that there shall be only two MRI scanners in the area." False. The Committee is convinced that there is good reason, cogent historical evidence, and practical wisdom is holding that more than two imagers should be introduced into greater Hartford. But the Committee also has a ton of evidence that a laissez-faire proposal whereby all the "big" hospitals who might be able to finance one should immediately have one is neither responsible vis-a-vis *total* health care imperatives nor capable of practical fulfillment in view of regulatory power. The Committee says we ought to *begin* with at least two MRI units, that their proper utilization and clinical benefit should swiftly convince all concerned that more are needed soon, and that if any single hospital wants to take a solo flight on this question they are most welcome since that is their inalienable right.

The authors' comment that the Consortium plan would leave both Hartford and Saint Francis Hospitals without an *in situ* imager is correct. In fact, it would leave 13 hospitals of the Consortium, except John Dempsey Hospital, without an *in situ* machine unless, as previously indicated, any Consortium member feels compelled to get a machine for their exclusive use. That remains their right and their privilege. In essence, the Consortium plan is to do something on a practical, clinically efficient and cost effective basis in introducing a new technology to our area on a collaborative basis. We are not in the business of telling our members what they cannot do. We are a voluntary organization in which any member has the right of dissent, whether verbal or printed.

The authors' case of the post-operative patient in the Ambu bag respirator is well taken. I would agree that a free-standing imager requiring a trip in an ambulance for such a patient is a nuisance and possibly a medical disaster. But even Hegel knew that the part, especially the small part, proves nothing about the whole. Current literature on the clinical uses of MRI clearly indicates that, at the present time, this technology is used in the large majority of time for ambulatory patients. I simply don't find the "worst case scenario" of the authors to be very convincing in view of what their professional colleagues have been telling us about the appropriate client for their machine.

Finally, the authors seem to lament the expenditure of $100,000 to professionally arrange for the legally mandated certificate of need. They opine that "one does not have to spend $100,000 to determine the obvious." I agree. But we aren't spending the money to determine that at least large acute care hospitals need MRI because that is truly obvious. We are spending it because there is a legal body called the Commission on Hospitals and Health Care in this state and groups like the Connecticut Business and Industry Association and the Hartford Business Coalition on Health who have managed to present to hospitals a very demanding set of criteria which are legally binding and which must be met if the project is to see the light of day. CON's are a royal pain to anybody but perhaps the authors could get a more nuanced perspective on the necessity for doing them professionally and well from the CEO's of the hospitals where they practice, in, for example, the matter of new surgical suites where they operate.

A last caution: Hegel died on November 14, 1831 in Berlin, not in 1832 as reputed by the authors. However, before he died, specifically in 1816, he authored his metaphysical masterpiece "Wissenschaft der Logik" when he was the Director of the Gymnasium in Nuremberg. Among so many of his pithy sayings one seems particularly apposite. He wrote: "Nothing so plagues the rigorous discipline of logic as the half-truth, the single fact disconnected from other more compelling facts and the *non-sequitur.*" In that sense, I would join the authors in proclaiming: "Hegel was right."

Rev. Thomas J. Lynch
Chairman

Capital Area Health Consortium,
Newington, CT

The above letter was referred to Drs. Roberts and Sadowski, who offer the following reply:

To the Editor: We thank Father Lynch for his comments. We are gratified that he agrees with all of our important points including: (1) any hospital with a major neurosurgical service should have a MRI scanner, (2) obstructionistic tactics of various cost control groups in the 1970's were largely responsible for the retarded introduction of the CT scanner in Connecticut, (3) there should be more than two MRI scanners in the greater Hartford area, (4) the present Consortium plan would leave the two hospitals with the largest neurosurgical services (Saint Francis and Hartford) without MRI scanners and, (5) the Connecticut task force of radiologists and laymen that concluded there should be only two scanners in the state is in error. Incidentally, we had our editorial reviewed prior to publication by one of the radiologists who was a member of the task force. He indicated that he was in agreement with our views.

The only substantive point that Father Lynch does not acknowledge is the most obvious. A Consortium owned freestanding MRI scanner can serve out-patients but would deprive acutely ill non-transportable patients the potentially life saving benefits of this new diagnostic tool. Conversely, if a scanner were installed in a hospital with a large number of acutely ill non-transportable patients (Hartford or Saint Francis), it would not only serve such patients but could also serve out-patients from the entire area. This would result in the greatest good for the greatest number, something that the present Consortium plan does not do.

Finally, we admit we goofed. Hegel died in 1831, not 1832.

Melville P. Roberts, M.D.
and Joseph S. Sadowski, M.D.

Hartford, CT

PRIVATE PSYCHIATRIC HOSPITALS IN CONNECTICUT

To the Editor: The Editor and staff of *Connecticut Medicine* deserve commendation for devoting the September issue to "Psychiatric Issues in Medicine." Unfortunately, the decision to limit the authors of the article in the special issue solely to the staff of the Institute of Living has resulted in a skewed picture of the role, services, and characteristics of the other psychiatric hospitals in Connecticut. Apparently, neither your research staff nor Dr. Conklin saw the need to check their "facts" with the hospitals they were describing. I will only address the disservice done to the Elmcrest Psychiatric Institute and leave the possible misrepresentation of the other hospitals to their respective staffs.

Elmcrest has 105 beds, *not* 99; it has 60 beds for in-patient services for children and adolescents, *not* just a day treatment program for adolescents as described; it has intensive family therapy programs and creative therapy activities programs, also not mentioned; and, finally, National Medical Enterprises is *not* the "parent company for Elmcrest"!

Elmcrest Psychiatric Institute is the first and only psychiatric hospital in Connecticut to enter into a progressive, innovative joint-venture-partnership between local mental health professionals (Marlborough Company, Inc. and Psychotherapy Associates of New Haven) and national hospital management corporations (Psychiatric Institutes of America, 1971, and National Medical Enterprises, 1982). The successful outcome has been, and continues to be, efficient, cost-effective, non-clinical business management of the hospital provided by PIA and NME, plus excellent clinical programs for patient care and treatment provided by Connecticut clinicians.

Dr. Conklin's article misrepresents Elmcrest as an absentee-ownership-franchise of a profit-oriented national hospital chain. This has provoked concern and dismay among the staff and patients at Elmcrest, as well as among the professional and general community-at-large. It is grossly unfair and misleading, and your published correction of this error would be much appreciated by the clinical staff as well as the present and future patients of Elmcrest.

Louis B. Fierman, M.D.
Senior Consultant

Elmcrest Psychiatric Institute
Portland, CT

The above letter was referred to Dr. Conklin, who offer the following reply.

To the Editor: I am writing in response to the letter of Louis B. Fierman, M.D., of Elmcrest Psychiatric Institute, who writes to decry misrepresentation and the use of improper "facts" in my article in the September 1985 issue of *Connecticut Medicine,* entitled "Private Psychiatric Hospitals in Connecticut: A Tradition of Excellence, A Future of Change."

The information and "facts" concerning the five private psychiatric hospitals other than the Institute of Living were solicited from each of the individual hospitals. The information used in the article concerning Elmcrest was received from the office of Dr. Lane Ameen, Medical Director of Elmcrest Psychiatric Institute. Any misinformation was provided by Elmcrest, and it is unfortunate that the material sent to me was either old or inaccurate. There certainly was no intention to misrepresent Elmcrest's hospital program. In fact, the intention of the article was to compliment each of the hospitals for the fine programs which each of them does provide.

Thomas J. Conklin, M.D.

The Institute of Living
Hartford, CT

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Timothy B. Norbeck, *Executive Director*
Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Shelley A. Marcus
Director of Government Relations

Council Meeting

Thursday, October 24, 1985

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahrens, Bobruff, Bonner, Czarsty, Dardick, Freedman, James, Kamens, McDonnell, Orphanos, Petrie, Ragusa, Reyelt, Jr., Robbins, Rose, Seide, Sullivan, Jr., Sweet, Villa, Waldron, Welch, Whalen, Jr., and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Dr. Fabro, Shelley A. Marcus, Mr. Meister (NHCMA), Mr. Coffey (HCMA), Mr. Tomat (FCMA) and Mrs. Ganguli (Auxiliary).

Absent were: Drs. Ahamed, Beck, Canzonetti, Friedberg, Kaess, Sadowski, Scheer, Schwartz and Zanker.

Reports from Physicians Serving on State and Federal Agencies

Dr. Guy W. Van Syckle reported that he has resigned from the HSA-V Board and that his successor had not as yet been named.

Staff report on CSMS Monitoring of Planning and Regulatory Agencies was received as information.

Several other actions were taken at this time concerning the medicare freeze which follows:

It was VOTED that the Council express concern at lack of public understanding of the difference between a freeze on government medical payments and one on physicians' charges.

It was further VOTED that the Connecticut State Medical Society and the American Medical Association pursue a more vigorous and clear presentation of the inequity and probable unconstitutionality of this prolonged price control of a single profession.

It was also VOTED that this action should be introduced at the AMA House of Delegates as a Connecticut resolution and that the matter also be referred to the Public Affairs Committee and the speakers bureaus for implementation.

It was VOTED that the Council supports the necessity of controlling medicare outlays and is sympathetic to caps on medicare payments to physicians, however, it opposes as unreasonable and untenable that the Federal Government can regulate what physicians may charge in view of increasing overhead. A cap on medicare payments to physicians without a cap on charges would allow the competitive free enterprise system to function in the best interest of quality care for patients.

It was VOTED to ask the Committee on Statewide Medical Planning to develop recommendations for CSMS action in support of physician members of CSMS charged for alleged violations under the Federal fee freeze law.

Report of the President

Dr. Whalen reported on the following items:

a. Meeting of County Presidents: Another dinner meeting for county presidents was held on September 26 and it is believed that these meetings are of reciprocal value in that it gives CSMS an insight as to what is going on in each county and also provides an opportunity for the county presidents to hold a dialogue on problems facing medicine.

b. Speakers' Bureaus: It is planned to develop a speakers' bureau in each county and a training session will be held on November 23. Each county has been requested to submit the names of physicians who will be willing to participate in these speakers' bureaus. The topics to be discussed will be primarily professional liability and it is believed that these speakers' bureaus will be an adjunct supportive of the legislative program. Remarks will be prepared concerning professional liability, but the speakers will also be given questions and answers about the medicare freeze and DRG's just in case the questions come up in their speaking engagements. Progress on the development of these speakers' bureaus will be reported on at a later date.

c. Leadership Conference: He reported that the leadership conference held on September 4 was quite successful and felt sure that the physicians who gave up a beautiful Saturday to attend this all day conference felt it was worthwhile.

d. Voluntary Hospital Association of America (VHA): Dr. Whalen expressed concern about the Voluntary Hospital Association of America entering Connecticut and believes it to be one of the biggest thrusts in splitting the hospitals in the state. The VHA, in a joint venture with Aetna, is about to incorporate in order to offer a PPO to approximately half the hospitals in Connecticut. As a counter move the remaining Connecticut hospitals have been aligning themselves with a new organization, Health Services of New England, which will probably offer a similar PPO. These types of hospital based network alliances generally have exclusionary policies which prevent participation by physicians and hospitals in both networks. Following discussion it was VOTED that CSMS immediately investigate the status of the emerging hospital-network PPO's in the State of Connecticut. The study should include the impact of these networks on the doctor-patient relationship and the results of the study be presented to the President of CSMS so that distribution of the report may be made to the membership and other involved parties.

e. Statewide IPA/HMO: Dr. Whalen brought to the attention of the Council the possibility of having a statewide IPA. A summary of information on the formation of the IPA/HMO in Georgia was distributed. Following lengthy discussion, the following action was taken: It was VOTED that an ad hoc committee be established immediately to study the feasibility and advisability of establishing a statewide IPA and/or HMO to report with recommendations for action to the House of Delegates on November 20. That the ad hoc committee be authorized to have access to legal counsel, if necessary. It was further VOTED that the Chairman of the Council appoint the committee of at least seven members.

Report of the Executive Director

Mr. Norbeck reported on the following items:

a. Governor's Conference on Victims of Crime: Invitations were extended to all members of the Council to attend this conference of Friday, November 22, 1985 at the Treadway-Cromwell Hotel, Cromwell, CT.

b. Staff Changes: It was announced that Richard Fiorentino has resigned his position at CSMS and was joining the Hartford County Medical Association staff and that Shelley Marcus, formerly of the Sullivan and LeShane staff has joined the CSMS staff. The Council wished Mr. Fiorentino well and gave him a standing ovation.

c. Speaking engagements: Mr. Norbeck reported that he had spoken to two groups of the League of Women Voters, the Lions Club, and appeared on a panel in Boston with representatives of the American Trial Lawyers Association on the subject of the medical malpractice insurance situation.

d. ATLA Report: Council members were asked to take with them a copy of the transcript of the AMA response to the Association of Trial Lawyers of America Statements regarding the professional liability crisis which were placed on the table. The documents contain valuable information and can be used as a reference.

Fiscal Subcommittee

a. **1986 Budget.**

Dr. McDonnell, Treasurer, presented the budget for 1986 and following discussion, the following actions were taken:

VOTED that CSMS membership dues for 1986 be set at $250.00;

VOTED that the 1986 Budget, as prepared by the Fiscal Subcommittee, be approved by the Council, and transmitted to the House of Delegates on November 20, 1986, with the Council's recommendation that the dues structure and budget be approved by the House;

VOTED that, in the interest of economy and efficiency, that all Journal activities be carried out from the Society's headquarters building and that the Torrington Journal office be phased out by July 1, 1986.

FCMA Board Actions

1. It was VOTED to refer the matter of the qualifications for Life Membership to the CSMS Council Subcommittee on Bylaws for its review and recommendations.
2. It was pointed out in discussion relative to the rapid growth of HMOs and PPOs in Connecticut that CSMS staff was attempting to develop its own area of expertise in order to be of help to physicians in such matters.
3. It was VOTED to receive for information the FCMA report on the Southern New England Telephone Company's latest expansion of the Yellow Pages which will be known as the Golden Opportunity Pages and focus on the senior citizen's guide to discounts and services.

Coalition on Medicare

Dr. Czarsty reported on a meeting held with county association staff members and representatives of the offices of congressional legislators to discuss the confusion among the medical community concerning the definition of "medically necessary" visits to Connecticut nursing homes, as well as the manner in which retroactive audits of physicians who have received medicare reimbursement are conducted by Connecticut General (CG).

It was VOTED to reconstitute the Ad Hoc Committee on Medicare provided this Committee is permitted by Connecticut General to have input into the Medicare Program, acting as liaison between CSMS and CG. In the event Medicare or HCFA does not agree to utilize the committee in this manner, The Committee shall not be activated.

It was VOTED to approve the expense of approximately $1500 for the preparation of a position paper by J. Charles Mokriski, of Day, Berry and Howard, outlining suggestions for improvements in the medicare reimbursement procedures concerning nursing homes.

Labor Union for Physicians

Kenneth Robbins, M.D., mentioned the recent mailing to all physicians by the Connecticut Federation of Physicians and Dentists. It was agreed that the item should be included on the agenda for the House of Delegates meeting on November 29, and that CSMS legal counsel have its comments available at the meeting. (See information distributed with handbook)

Life Members

It was VOTED to receive for information the following names of Life Members:

Name	Town
William F. Bauer, Jr.	Killingworth
Marcelle T. Bernard	East Norwalk
Robert S. Cleaver	Fairfield
Gerald H. Flamm	New Haven
Josephine Fuhrmann	Woodbridge
George J. Geanuracos	Bridgeport
George S. Hughes	Darien
Edmund D. Marinucci	East Norwalk
Thomas J. Masterson	Norwich
Louis Olore	Waterbury
Robert C. Olsen	New London
Douglas D. Perry	Clinton
Ray E. Persons	Meriden
Harold G. Plakins	Wallingford
Lloyd M. Wilcox, Sr.	Bristol

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on October 24, 1985. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

New Members

FAIRFIELD COUNTY

Martin B. Abrams, Danbury
Holly M. Bannister, Westport
Lawrence S. Beck, Fairfield
Joseph L. Belsky, Ridgefield
Kieve M. Berkwitz, Fairfield
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Joshua S. Jaffe, Sharon
Jedd F. Levine, Torrington
Jocelyn B. Manelis-Regenbogen, Torrington
Robert P. Noble, Lakeville
William F. Polito, Torrington
Antonio Scappaticci, Terryville
William R. Schmidt, Woodbury
Robert C. Schnurr, Sharon
Tomas N. Tomanek, Sharon

MIDDLESEX COUNTY

Claudia Borowiez, Middletown
Edward Cotlier, Middletown
Julie Flagg, Middletown
Joseph Fuller, Jr., Old Saybrook
John Hornby, Essex
David Miner, Middletown
Russell Munson, Chester
Edward Opalacz, Jr., Middletown

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Milford Hospital, a 150-bed J.C.A.H. recognized, full-service community hospital, located on the Connecticut shoreline is currently seeking an experienced Emergency Room physician. This full-time position offers a competitive starting salary and excellent fringe benefit package. Easily accessible by car, rail or air. Milford is a shoreline community of approximately 53,000. Submit resumes in confidence to: Monique M. Mauritz, Assistant Director of Personnel, Milford Hospital, 2047 Bridgeport Ave., Milford, CT 06460.

FAMILY PRACTICE

Family or General Practitioner wanted for extended hours Family Practice located in the beautiful Connecticut shoreline community. Mature physician desired, industrial experience helpful. No hospital or night work. Write, CSMS, c/o FP/NK.

Family practitioner. University-based HMO seeks inquiries and applications for staff positions. Competitive salary and benefits programs. Contact, Medical Director, Yale University Health Services, 17 Hillhouse Ave., New Haven, CT 06520. (Tel. 203-436-8433).

Established, prepaid staff model HMO seeks an experienced board-eligible/certified family practitioner to staff our Wallingford Health Center. Unusual opportunity to meet the community's primary care needs where continuity of care, patient education/preventive medicine and high quality personal style are emphasized. CHCP has 42,000 members and is affiliated with Yale-New Haven Medical Center. Liberal benefit package. One opening available immediately, another starting July 1, 1986. Send C.V. and salary requirements to: Medical Director, Community Health Care Plan, Inc., 221 Whitney Avenue, New Haven, CT 06511. EOE M/F.

INTERNAL MEDICINE

Three-man internal medicine/cardiology group seeks BC/BE internist. Contact Dr. Hilliard Spitz, 447 Montauk Ave., New London, CT 06320. (203) 447-1426.

OBSTETRICS/GYNECOLOGY

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population base; central location. Excellent opportunity for affiliation with a progressive Medical and Administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OB/WW.

OTOLARYNGOLOGY

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population; central location. Excellent opportunity for affiliation with a progressive medical and administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o OTO/WW.

PRIMARY CARE

Quality primary care physician needed to join internist and ER physician as a partner in developing a dynamic ambulatory care center in southern Connecticut. Those with serious interest should send CV and cover letter to CSMS, c/o PC/SS.

Primary Care Physicians, Family Practitioners, Internist needed to join our expanding Walk-In Medical Centers. Full-time position available. Compensation package includes competitive salary, malpractice insurance, and profit sharing opportunity. Flexible scheduling. Send C.V. to Family Walk-In Medical Center, 111 Mattatuck Heights, Waterbury, CT 06704.

Walk-In Medical Services is seeking full and part-time physicians to work in a convenience medical facility in Orange, CT. Family practice/Internal medicine preferred. Reply to CSMS, PC/RBH.

PSYCHIATRY

Cedarcrest Hospital, Newington, a 130 bed facility has a position for part time psychiatrist to work with a treatment team in the care of acute and intermediate care psychiatric patients. Night call also available if desired. Contact Arnold W. Johnson, Jr., M.D., Chief of Professional Services (203) 666-4613.

RADIOLOGY

Hospital based general diagnostic radiologist with special interest and training in invasive radiology is being recruited by six man radiology group for 100 plus general hospital in Northeastern Connecticut. Individual must have depth of experience necessary to initiate and manage interventional procedure program. Hospital currently offers full range of service including nuclear medicine, ultrasound, and mobile CT scan unit. New one-day surgical center just completed, also regional dialysis center and busy out-patient department. Send curriculum vitae to Jonathan Berger, M.D., 142 Echo Drive, Vernon, CT 06066.

Radiologist, planning retirement, seeks partner in busy, private practice. Write, CSMS, RAD/EE.

UROLOGY

Central Connecticut. Full service community hospital wishes to attract solo practitioner, BC/BE, for private practice. Growing population; central location. Excellent opportunity for affiliation with a progressive medical and administrative staff. Incentive program available to qualified applicant. Send CV to CSMS, c/o UR/WW.

PHYSICIANS WISHING TO LOCATE IN THE STATE OF CONNECTICUT

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Mature family physician, B/C, with many years of experience including industrial medicine, seeks full-time work in a medical facility in southern Connecticut. Please call (203) 372-0458.

Mature Family physician, B/C, with many years of experience including industrial medicine, seeks full time work in a medical facility in Southern Connecticut. Please call (203) 372-0458.

GENERAL SURGERY

Jan. '86. Age 35. Presently in practice. Nat'l bds. AB cert. MD, Cornell University Medical College; Int., University of Texas; Res., St. Lukes-Roosevelt Hospital, NYC. Prefers group, associate or institutional type practice. Write CSMS, c/o BAB/SUR.

July '86. Age 30. Nat'l bds. AB elig. MD, University of Chicago; Int. and Res., Massachusetts General Hospital; Fellowship, University of Chicago. Prefers group practice. Write, Steven H. Untracht, M.D., 224 Kennedy Drive, #310, Malden, MA 02148.

Oct. '86. Age 32. Presently in practice. Nat'l bds. AB cert. MD, Albany Medical College; Int. and Res., St. Elizabeth's Hospital, Boston, MA. Prefers group practice. Write Richard K. Howard, M.D., 10202 Parkwood Drive, Kensington, MD 20895.

INTERNAL MEDICINE

July '86. Age 30. FLEX. AB elig. MD, University of Rome, Rome, Italy; Int. and Res., Framingham Union Hospital, Framingham, MA. Prefers group or associate type practice. Write, Thomas A. Hanna, M.D., 16 Trinity Drive, Milford, MA 01757.

July '86. Licensed in Connecticut. Age 28. Nat'l bds. AB elig. MD, University of Pennsylvania School of Medicine; Int. and Res., Hartford Hospital, Hartford, CT. Prefers group or associate type practice. Write, Eric L. Rosenberg, M.D., 100 Laura Lane, Apt. C-2, Rocky Hill, CT 06067.

Oct. '85. Age 29. FLEX. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital, Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional, or HMO type practice. Write, Nancy Irene Hoffmann-Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

Oct. '85. Age 36. Nat'l bds. AB elig. MD, St. George's University School of Medicine, Grenada, British West Indies; Int., Franklin Square Hospital Baltimore, MD; Res., Texas Tech University School of Medicine, Amarillo, TX. Prefers group, institutional or HMO type practice. Write, Dom P. Wadhwa, M.D., One M Maidstone Court, Baltimore, MD 21237.

CARDIOLOGY. July '86. Nat'l bds. AB cert. MD, Hahneman University, Philadelphia, PA; Int., Res. and Fellowship, Long Beach Va Medical Center, Long Beach, CA. Experienced in angioplasty, pacemakers, nuclear medicine and doppler/echocardiography. Prefers group or associate type practice. Write, Brian C. Swirsky, M.D., 311 Ocean Ave., Apt. A, Seal Beach, CA 90740.

GASTROENTEROLOGY. July '86. Age 30. FLEX. AB cert. MD, Georgetown University School of Medicine, Washington, DC; Int. and Res., St. Elizabeth's Hospital, Tufts University, Brighton, MA; Fellowship, The Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC. Prefers group, associate or institutional type practice. Write, Thomas P. McMahon, M.D., Brookway West Condominium #E-8, Lewisville, NC.

PULMONARY. July '86. Age 30. Nat'l bds. AB cert. (IM), AB elig. (PUL). MD, University of Connecticut Health Center, Farmington, CT; Int. and Res., McGaw Medical Center, Northwestern Memorial Hospital, Chicago, IL; Fellowship, Cedars-Sinai Medical Center, Los Angeles, CA. Preference is for a pulmonary practice either hospital-based, a subspecialty group or a multi-specialty group. Write, Harlan R. Weinberg, M.D., 337 N. Palm Dr., #8, Beverly Hills, CA 90210.

PULMONARY. July '86. Licensed in Connecticut. Age 30. Nat'l bds. AB cert. MD, Johns Hopkins, Baltimore, MD; Int. and Res., University of Chicago, Chicago, IL; Fellowship, Yale-New Haven Hospital. Prefers group or associate type practice. Write, Ilene L. Rosenberg, M.D., 574 Skiff St., North Haven, CT 06473.

PULMONARY. Immediately available. Presently in practice. Age 32. AB Cert. MD, University of Bombay, Bombay, India; Int. and Res., Jewish Hospital and Medical Center, Brooklyn, NY; Fellowship, Coney Island Hospital, Queens, NY. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Viswanath P. Vasudevan, M.D., 102-12 65th Ave., Apt. #D-64, Forest Hills, NY 11375.

PULMONARY. July '86. Age 30. Nat'l bds. AB cert. MD, Duke University; Int. and Res., Vanderbilt; Fellowship, NYU and Vanderbilt. Prefers group or associate type practice in a medium to large-sized community. Write, Jon Jay Tumen, M.D., 171-A Kenner Ave., Nashville, TN 37205.

RHEUMATOLOGY. July '86. Age 29. Nat'l bds. AB cert. MD, Mount Sinai School of Medicine; Int. and Res., Mount Sinai Hospital, NYC; Fellowship, Mount Sinai Medical Center. Prefers group or associate type practice. Write, Richard P. Crane, M.D., 1249 Park Ave., #17B, New York, NY 10029.

OBSTETRICS/GYNECOLOGY

Oct. '85. Age 34. Presently in practice. FLEX. AB elig. MD, Autonomous University of Guadalajara, Mexico; Fifth Pathway, University of Maryland; Res., Prince George's General Hospital and Medical Center, Cheverly, MD. Prefers group type practice or closed panel HMO in a medium-sized community. Write Gregory S. Rein, M.D., RR#1, Box 500, Woolwich, ME 04579.

PART TIME

Negotiable availability. Licensed in Connecticut. Presently in practice. Age 43. Nat'l bds. AB elig. MD, Int. and Res., India; Fellowship, William S. Hall of Psychiatry. Interested in all types of practice but only part-time. Write, Naimetulla A. Syed, M.D., Fairfield Hills Hospital, Newtown, CT 06470.

PEDIATRICS

July '85. Age 31. Presently in practice. Nat'l bds. AB cert. MD, New York University School of Medicine; Int. and Res., Rhode Island Hospital. Prefers solo, group, or associate type practice in a large to medium-sized community. Write, Andrew J. Schuman, M.D., RFD 2, Box 249B, Caribou, ME 04736.

PRIMARY CARE

Feb. '86. Age 32. AB elig. MD, University of Rome, Rome, Italy; Int., Long Island College Hospital, Brooklyn, NY; Res., Illinois Masonic Medical Center, Chicago, IL. Prefers group, associate or HMO type practice in a medium-sized community preferably in western Connecticut. Write, Eli R. Goldner, M.D., 2841 West Rosemont, Chicago, IL 60659.

RADIOLOGY

July '86. Age 29. Nat'l bds. AB elig. MD, SUNY at Downstate; Int., Staten Island Hospital; Res., SUNY Downstate; Fellowship, Cornell Medical College at North Shore University Hospital. Prefers solo, group, associate, institutional or industrial type practice. Write, Daniel J. Cohen, M.D., 167 First Ave., Apt. #7, New York, NY 10003.

SURGERY

SURGICAL ONCOLOGY. Jan. '86. Age 38. Nat'l bds. AB cert. MD, Int., American University of Beirut, Lebanon; Res., St. Luke's-Roosevelt Hospital, NYC; Fellowship, Memorial Sloan Kettering Cancer Center, NYC. Prefers group, associate or institutional type practice. Write, CSMS, c/o ASM/SUR.

UROLOGY

July '86. Age 33. Nat'l bds. AB elig. MD, Boston University School of Medicine. Boston, MA; Int. and Res., Vanderbilt University Hospital, Nashville, TN. Experienced in adult and pediatric urology. Prefers group or associate type practice in a medium to large-sized community. Write, Ned R. Novsam, M.D., 8300 Sawyer Brown Rd., E-306, Nashville, TN 37221.

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